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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2022
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number 001-36714

JAGUAR HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**46-2956775**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

200 Pine Street, Suite 400
San Francisco, California 94104
(Address of principal executive offices, zip code)

(415) 371-8300
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock, Par Value $0.0001 Per Share	JAGX	The NASDAQ Capital Market

As of November 14, 2022 there were 143,222,568 shares of voting common stock, par value $0.0001 per share, outstanding, 2,014,131 shares of non-voting common stock, par value $0.0001 per share, outstanding (convertible into 639 shares of voting common stock).

PART I. — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)	September 30, 2022	December 31, 2021
Assets	(unaudited)	
Current assets:		
Cash	$ 10,561	$ 17,051
Accounts receivable	1,825	1,709
Other receivable	634	435
Inventory	6,601	4,900
Prepaid expenses and other current assets	5,587	4,339
Total current assets	25,208	28,434
Property and equipment, net	572	650
Operating lease - right-of-use asset	1,104	1,084
Intangible assets, net	22,561	22,651
Other assets	1,842	446
Total assets	$ 51,287	$ 53,265
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,285	$ 4,929
Accrued liabilities	8,504	7,117
Warrant liability	—	1
Operating lease liability, current	418	240
Notes payable, current	11,737	3,184
Series D perpetual preferred stock: $0.0001 par value; 977,300 shares authorized at September 30, 2022 and December 31, 2021; zero shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Total current liabilities	26,944	15,471
Operating lease liability, net of current portion	738	919
Notes payable, net of discount, net of current portion (includes hybrid instrument designated at Fair Value Option amounting to $7.2 million and $7.8 million as of September 30, 2022 and December 31, 2021, respectively)	20,006	25,022
Total liabilities	47,688	41,412
Commitments and contingencies (See Note 7)		
Stockholders' equity		
Series B-2 convertible preferred stock: $0.0001 par value, 10,165 shares authorized at September 30, 2022 and December 31, 2020; zero shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Series C perpetual preferred stock: 1,011,000 shares authorized at September 30, 2022 and December 31, 2020; zero shares issued and outstanding at September 30, 2022 and December 31, 2020	—	—
Common stock - voting: $0.0001 par value, 298,000,000 shares authorized at September 30, 2022 and December 31, 2021; 135,844,151 and 48,352,527 issued and outstanding at September 30, 2022 and December 31, 2021	13	5
Common stock - non-voting: $0.0001 par value, 50,000,000 shares authorized at September 30, 2022 and December 31, 2021; 2,120,786 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	263,001	231,100
Noncontrolling interest	(48)	242
Accumulated deficit	(259,367)	(219,494)
Total stockholders' equity	3,599	11,853
Total liabilities and stockholders' equity	$ 51,287	$ 53,265

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue	$ 3,150	$ 630	$ 8,696	$ 2,255
Operating expenses				
Cost of product revenue	613	617	1,524	1,864
Research and development	5,940	3,312	13,336	9,597
Sales and marketing	2,109	2,261	7,089	6,596
General and administrative	4,384	3,969	14,876	12,450
Series 3 warrants inducement expense	—	—	—	1,462
ELOC warrants inducement expense	—	—	—	172
Total operating expenses	13,046	10,159	36,825	32,141
Loss from operations	(9,896)	(9,529)	(28,129)	(29,886)
Interest expense	(2,731)	(2,078)	(10,089)	(5,988)
Loss on extinguishment of debt	—	—	(2,187)	(753)
Change in fair value of financial instruments and hybrid instrument designated at Fair Value Option	176	(565)	652	(1,639)
Other expense, net	(158)	(20)	(410)	(16)
Loss before income tax	(12,609)	(12,192)	(40,163)	(38,282)
Income tax expense	—	—	—	—
Net loss and comprehensive loss	(12,609)	(12,192)	(40,163)	(38,282)
Net loss attributable to noncontrolling interest	(89)	—	(290)	—
Net loss attributable to common shareholders	$ (12,520)	$ (12,192)	$ (39,873)	$ (38,282)
Net loss per share, basic and diluted	$ (0.12)	$ (0.27)	$ (0.49)	$ (0.87)
Weighted-average common shares outstanding, basic and diluted	106,362,178	45,840,262	81,657,061	44,167,885

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES
IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(Unaudited)

(In thousands, except share data)	Common Stock - voting Shares	Common Stock - voting Amount	Common Stock - non-voting Shares	Common Stock - non-voting Amount	Additional paid-in capital	Noncontrolling interest	Accumulated deficit	Total Stockholders' Equity
Balances as of June 30, 2022	85,170,109	$ 9	2,120,786	$ —	$ 249,554	$ 41	$ (246,847)	$ 2,757
Shares issued to Streeterville in exchange of notes payable and accrued interest	23,264,705	2	—	—	5,054	—	—	5,056
Shares issued in At the Market offering, net of issuance and offering costs of $3	22,765,948	2	—	—	6,220	—	—	6,222
Shares issued to Iliad in exchange of notes payable and accrued interest	2,365,930	—	—	—	792	—	—	792
Shares issued to Synworld for services	2,251,689	—	—	—	633	—	—	633
Shares issued to other third party for services	12,000	—	—	—	2	—	—	2
Shares issued upon exercise of restricted stock units	13,207	—	—	—	4	—	—	4
Shares issued upon exercise of stock options	1,263	—	—	—	1	—	—	1
Stock-based compensation	—	—	—	—	741	—	—	741
Net loss	—	—	—	—	—	(89)	(12,520)	(12,609)
Balances as of September 30, 2022	**135,844,851**	**$ 13**	**2,120,786**	**$ —**	**$ 263,001**	**$ (48)**	**$ (259,367)**	**$ 3,599**

(In thousands, except share data)	Common Stock - voting Shares	Common Stock - voting Amount	Common Stock - non-voting Shares	Common Stock - non-voting Amount	Additional paid-in capital	Noncontrolling interest	Accumulated deficit	Total Stockholders' Equity
Balances as of June 30, 2021	45,773,998	$ 5	2,120,786	$ —	$ 224,769	$ —	$ (192,989)	$ 31,785
Shares issued in PIPE financing	309,242	—	—	—	776	—	—	776
Shares issued to third party for services	5,666	—	—	—	16	—	—	16
Shares issued upon exercise of stock options	1,851	—	—	—	2	—	—	2
Shares issued on conversion of Napo merger common shares	124	—	—	—	—	—	—	—
Fractional shares	50	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,165	—	—	1,165
Net loss	—	—	—	—	—	—	(12,192)	(12,192)
Balances as of September 30, 2021	**46,090,931**	**$ 5**	**2,120,786**	**$ —**	**$ 226,728**	**$ —**	**$ (205,181)**	**$ 21,552**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES
IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(Unaudited)

(In thousands, except share data)	Common Stock - voting Shares	Common Stock - voting Amount	Common Stock - non-voting Shares	Common Stock - non-voting Amount	Additional paid-in capital	Noncontrolling interest	Accumulated deficit	Total Stockholders' Equity
Balances as of January 1, 2022	48,352,527	$ 5	2,120,786	$ —	$ 231,100	$ 242	$ (219,494)	$ 11,853
Shares issued in At the Market offering, net of issuance and offering costs of $103	49,580,691	5	—	—	17,781	—	—	17,786
Shares issued to Streeterville in exchange of notes payable and accrued interest	23,264,705	2	—	—	5,054	—	—	5,056
Shares issued to Iliad in exchange of notes payable and accrued interest	12,159,573	1	—	—	5,491	—	—	5,492
Shares issued to Synworld for services	2,251,689	—	—	—	633	—	—	633
Shares issued to other third party for services	47,000	—	—	—	21	—	—	21
Shares issued upon exercise of restricted stock units	187,403	—	—	—	99	—	—	99
Shares issued upon exercise of stock options	1,263	—	—	—	1	—	—	1
Stock-based compensation	—	—	—	—	2,821	—	—	2,821
Net loss	—	—	—	—	—	(290)	(39,873)	(40,163)
Balances as of September 30, 2022	**135,844,851**	**$ 13**	**2,120,786**	**$ —**	**$ 263,001**	**$ (48)**	**$ (259,367)**	**$ 3,599**

(In thousands, except share data)	Common Stock - voting Shares	Common Stock - voting Amount	Common Stock - non-voting Shares	Common Stock - non-voting Amount	Additional paid-in capital	Noncontrolling interest	Accumulated deficit	Total Stockholders' Equity
Balances as of January 1, 2021	38,007,420	$ 4	2,120,786	$ —	$ 184,097	$ —	$ (166,899)	$ 17,202
Shares issued on exercise of Series 1, Series 2, and 2019 Bridge Note Warrants	1,383,524	—	—	—	2,034	—	—	2,034
Shares issued in PIPE financing	725,906	—	—	—	1,751	—	—	1,751
Shares issued in At the Market offering, net of issuance and offering costs of $311	669,850	—	—	—	5,365	—	—	5,365
Shares issued to Iliad in exchange of notes payable and accrued interest	588,235	—	—	—	2,982	—	—	2,982
Shares issued to third party for services	5,666	—	—	—	16	—	—	16
Shares issued in registered public offering, net of issuance and offering costs of $2,550	4,028,290	1	—	—	23,233	—	—	23,234
Shares issued in extinguishment of Exchange Note 2	471,202	—	—	—	2,516	—	—	2,516
Shares issued on exercise of Series 3 warrants	206,915	—	—	—	1,776	—	—	1,776
Shares issued upon exercise of stock options	3,147	—	—	—	4	—	—	4
Shares issued on conversion of Napo merger common shares	726	—	—	—	—	—	—	—
Fractional shares	50	—	—	—	—	—	—	—
Warrants issued to Oasis for ELOC amendment, net of offering costs of $48	—	—	—	—	124	—	—	124
Registered public offering costs	—	—	—	—	—	—	—	—
At the Market offering costs	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,830	—	—	2,830
Net loss	—	—	—	—	—	—	(38,282)	(38,282)
Balances as of September 30, 2021	**46,090,931**	**$ 5**	**2,120,786**	**$ —**	**$ 226,728**	**$ —**	**$ (205,181)**	**$ 21,552**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash flows from operating activities		
Net loss	$ (40,163)	$ (38,282)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt issuance costs, debt discount, and non-cash interest expense	8,791	3,633
Stock-based compensation	2,821	2,832
Loss on extinguishment of debt, net	2,187	753
Depreciation and amortization expense	1,482	1,290
Shares issued in exchange for services	654	16
Amortization of operating lease - right-of-use-asset	208	45
Shares issued upon exercise of restricted stock units	99	—
Shares issued upon exercise of stock options	1	—
Change in fair value of financial instruments and hybrid instrument designated at Fair Value Option	(652)	1,639
Series 3 warrants inducement expense	—	1,462
Derecognition of debt discount on settlement of receivables secured borrowing	—	49
Changes in assets and liabilities		
Accounts receivable	(116)	2,421
Other receivable	(336)	(66)
Inventory	(1,701)	(1,731)
Prepaid expenses and other current assets	(1,249)	(1,369)
Other assets	(1,395)	37
Accounts payable	1,391	(986)
Accrued liabilities	1,508	2,002
Operating lease liability	(211)	36
Total cash used in operating activities	(26,681)	(26,047)
Cash flows from investing activity		
Purchase of equipment	(77)	(6)
Purchase of intangible assets	(1,237)	—
Advances for future capital investment	—	(10,478)
Total cash used in investing activity	(1,314)	(10,484)
Cash flows from financing activities		
Proceeds from issuance of shares in At the Market offering, net of issuance and offering costs of $103 and $311	17,786	5,365
Proceeds from notes payable with Streeterville	3,975	—
Repayment of insurance financing	(118)	(588)
Payment of Tempesta Note	(100)	—
Proceeds from issuance of shares in registered public offering, net of issuance and offering costs of $2,550	—	23,232
Proceeds from issuance of notes payable, net of issuance costs of $50	—	10,975
Proceeds from issuance of shares on conversion of Series 1, Series 2, and 2019 Bridge Note warrants	—	2,034
Proceeds from issuance of shares in PIPE financing	—	1,751
Repayment of receivables secured borrowing	—	(1,822)
Payment of ELOC warrants offering costs	—	(35)
Repayment of notes payable	—	(100)
Proceeds from exercise of stock options	—	4
Total cash provided by financing activities	21,543	40,816
Effects of foreign exchange rate changes on assets and liabilities	(38)	—
Net (decrease) increase in cash	(6,490)	4,285
Cash at beginning of period	17,051	8,090
Cash at end of period	$ 10,561	$ 12,375

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

(Unaudited)

	Nine Months Ended	
	September 30, 2022	September 30, 2021
Supplemental schedule of cash flow information		
Cash paid for interest	$ 17	$ 21
Supplemental schedule of non-cash financing and investing activities		
Shares issued to Iliad in exchange of notes payable and accrued interest	$ 5,492	$ 2,982
Shares issued to Streeterville in exchange of notes payable and accrued interest	$ 5,056	$ —
Recognition of operating lease - right-of-use asset and operating lease liability	$ 223	$ 1,087
Shares issued on exercise of Series 3 warrants	$ —	$ 1,776
Insurance financing	$ —	$ 1,183
Offering costs included in accounts payable and accrued liabilities	$ —	$ (13)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

JAGUAR HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Jaguar Health, Inc. ("Jaguar" or the "Company") was founded in San Francisco, California as a Delaware corporation on June 6, 2013 (inception). The Company was a majority-owned subsidiary of Napo until the close of the Company's initial public offering on May 18, 2015. The Company was formed to develop and commercialize first-in-class prescription and non-prescription products for companion and production animals and horses. The Company's first non-prescription commercial products, Neonorm Calf and Neonorm Foal, were launched in 2014 and 2016, respectively.

On July 31, 2017, Jaguar completed a merger with Napo pursuant to the Agreement and Plan of Merger dated March 31, 2017, by and among Jaguar, Napo, Napo Acquisition Corporation ("Merger Sub"), and Napo's representative (the "Merger Agreement"). In accordance with the terms of the Merger Agreement, upon the completion of the merger, Merger Sub merged with and into Napo, with Napo surviving as the wholly owned subsidiary (the "Merger" or "Napo Merger"). Immediately following the Merger, Jaguar changed its name from "Jaguar Animal Health, Inc." to "Jaguar Health, Inc." Napo now operates as a wholly owned subsidiary of Jaguar focused on human health including the ongoing development of crofelemer and commercialization of Mytesi.

On March 15, 2021, Jaguar established Napo EU S.p.A (which changed its name in December 2021 to "Napo Therapeutics") in Milan, Italy as a subsidiary of Napo. Napo Therapeutics' core mission is to provide access to crofelemer in Europe to address significant rare/orphan disease indications, including, initially, two key orphan target indications: Short bowel syndrome (SBS) and congenital diarrheal disorders (CDD) with intestinal failure.

Crofelemer was granted orphan drug designation (ODD) for SBS in 2021 by the European Medicines Agency (EMA) and by the US Food and Drug Administration in 2017, and was granted ODD by the EMA in October 2022 for microvillus inclusion disease (MVID), a rare congenital diarrheal disorder (CDD) condition. Napo Therapeutics is initiating efforts to commence clinical development of crofelemer in SBS and CDD patients in support of the company's key focus on leveraging the EMA's accelerated conditional marketing authorization pathway in Europe for these rare diseases. Jaguar is currently supporting an investigator-initiated proof-of-concept study of crofelemer in patients with SBS or CDD with intestinal failure, with a planned endpoint of reduction of requirement of weekly volume of parenteral nutrition. The investigator is targeting a presentation in December 2022 of initial data from the study at a global GI conference in Dubai. In accordance with the guidelines of specific EU countries, publications of such data could support early patient access of crofelemer for SBS or CDD with intestinal failure by mid-2023 through programs in Europe for these devastating diseases for which there is a significant unmet medical need.

SBS affects approximately 10,000 to 20,000 people in the U.S., according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size. Despite limited treatment options, the global SBS market exceeded $568 million in 2019 and is expected to reach $4.6 billion by 2027, according to a report by Vision Research Reports.

Most of the activities of the Company are focused on the commercialization of Mytesi and Canalevia-CA1 and the ongoing clinical development of crofelemer for the prophylaxis of diarrhea in adult patients receiving targeted cancer therapy (CTD). Napo's pivotal On Target Phase 3 clinical trial of crofelemer for prophylaxis of CTD was initiated in October 2020 and is ongoing. In the field of animal health, we are continuing limited activities related to developing and commercializing first-in-class gastrointestinal products for dogs, dairy calves and foals.

Crofelemer is a novel, first in class anti secretory agent which has a normalizing effect on electrolyte and fluid balance while acting locally in the gut, and this mechanism of action has the potential to benefit multiple disorders that cause gastrointestinal distress, including diarrhea and abdominal discomfort. Crofelemer is in development for multiple possible follow-on indications in addition to SBS, CDD, and prophylaxis for cancer therapy related diarrhea (CTD), including management of diarrhea and abdominal discomfort in inflammatory bowel disease (IBD); diarrhea-predominant irritable bowel syndrome (IBS-D); and for idiopathic/functional diarrhea. A second-generation proprietary

anti-secretory agent, NP-300, is undergoing preclinical development for symptomatic relief and treatment of diarrhea in patients with acute infection from cholera.

We believe Jaguar is poised to realize a number of synergistic, value adding benefits—and the above-referenced expanded pipeline of potential blockbuster human indications of crofelemer and NP-300—upon which to build global partnerships. Jaguar, through Napo, holds global unencumbered rights for crofelemer, Mytesi, and Canalevia-CA1. Additionally, several of the drug product opportunities in Jaguar's crofelemer pipeline are backed Phase 2 and proof of concept evidence from human clinical trials.

Nasdaq Communication and Compliance

Minimum Bid Price Requirement

On February 17, 2022 the Company received a letter from the Staff of Nasdaq indicating that the bid price of the Company's common stock for the last 30 consecutive business days had again closed below the minimum $1.00 per share required for the continued listing under Nasdaq Listing Rule 5550(a)(2).

Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has been granted a 180-calendar day grace period, or until August 16, 2022, to regain compliance with the minimum bid price requirement. The continued listing standard will be met if the Company evidences a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day grace period. On August 18, 2022, the Company received a notification letter from the Staff notifying the Company that it had been granted an additional 180 days, or until February 13, 2023, to regain compliance with the Minimum Bid Price Requirement based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market with the exception of the bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period. In the event the Company does not regain compliance with the $1.00 bid price requirement by February 13, 2023, Nasdaq will provide written notification that the Company's securities will be delisted. At that time, the Company may appeal Nasdaq's determination to a Hearings Panel with a plan to regain compliance.

The Company is diligently working to evidence compliance with the minimum bid price requirement for continued listing on Nasdaq; however, there can be no assurance that the Company will be able to regain compliance or that Nasdaq will grant the Company a further extension of time to regain compliance, if necessary. If the Company fails to regain compliance with the Nasdaq continued listing standards, its common stock will be subject to delisting from Nasdaq.

Liquidity and Going Concern

The Company, since its inception, has incurred recurring operating losses and negative cash flows from operations and has an accumulated deficit of $259.4 million as of September 30, 2022. The Company expects to incur substantial losses and negative cash flows in future periods. Further, the Company's future operations, including the operations of substantially owned Italian subsidiary, Napo Therapeutics S.p.A., which include the satisfaction of current obligations, are dependent on the success of the Company's ongoing development and commercialization efforts, as well as securing additional financing and generating positive cash flows from operations. There is no assurance that the Company will have adequate cash balances to maintain its operations.

Although the Company plans to finance its operations and cash flow needs through equity and/or debt financing, collaboration arrangements with other entities, license royalty agreements, as well as revenue from future product sales, the Company does not believe its current cash balances are sufficient to fund its operating plan through one year from the issuance of these unaudited condensed consolidated financial statements. The Company has an immediate need to raise cash. There can be no assurance that additional funding will be available to the Company on acceptable terms, or on a timely basis, if at all, or that the Company will generate sufficient cash from operations to adequately fund operating needs. If the Company is unable to obtain an adequate level of financing needed for the long-term development and commercialization of our products, the Company will need to curtail planned activities and reduce

costs. Doing so will likely have an adverse effect on our ability to execute our business plan; accordingly, there is substantial doubt about the ability of the Company to continue in existence as a going concern. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and on a basis consistent with the annual consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2022, or for any other future annual or interim period. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Annual Report on Form 10-K for the year ended December 31, 2021. The condensed consolidated balance sheet at December 31, 2021 has been derived from the audited consolidated financial statements at that date, but does not include all disclosures, including notes, required by U.S. GAAP for complete financial statements.

There has been no material change to the Company's significant accounting policies during the three and nine months ended September 30, 2022, as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's Annual Report on Form 10-K as of and for the year ended December 31, 2021, which was filed to SEC on March 11, 2022.

Except as noted above, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly the financial position as of September 30, 2022, results of operations for the three and nine months ended September 30, 2022, and 2021, changes in convertible preferred stock and stockholders' equity for the three and nine months ended September 30, 2022, and 2021, and cash flows for the nine months ended September 30, 2022, and 2021. The interim results are not necessarily indicative of the results for any future interim periods or for the entire year.

Principles of Consolidation

The unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and applicable rules and regulations of the Securities and Exchange Commission ("SEC") and include the accounts of the Company and its wholly-owned subsidiary. All inter-company transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires the Company's 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, valuation of hybrid instruments designated at fair value option ("FVO"), valuation of 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.

In March 2020, the World Health Organization declared the COVID-19 outbreak to be a pandemic. During the period ended September 30, 2022, the Company's financial results were not significantly affected by the COVID-19 outbreak. The Company has considered all information available as of the date of issuance of these financial statements and the Company is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. The extent to which the COVID-19 outbreak affects the Company's future financial results and operations will depend on future developments which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the outbreak, and current or future domestic and international actions to contain and treat it. For a discussion of risks of COVID-19 relating to the Company's business, see "Item 1A. - Risk Factors- Risks Related to Our Business- The novel coronavirus global pandemic could adversely impact our business, including our supply chain, clinical trials and commercialization of Mytesi and Canalevia-CA1."

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, 2022 and December 31, 2021.

Accounts Receivable

Accounts receivable is recorded net of allowances for discounts for prompt payment and credit losses. The Company estimates an allowance for credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in general and administrative expenses. The credit loss allowance was immaterial as of September 30, 2022 and December 31, 2021. In addition, the Company writes off an uncollectible accounts receivable that have a contractual maturity of one year or less when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery.

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 are generally in excess of Federal Deposit Insurance Corporation insurance limits.

For the three and nine months ended September 30, 2022, and 2021, substantially all of the Company's revenue was derived from the sale of Mytesi. In looking at sales by the Company to distributors whose net revenue percentage of total net revenue was equal to or greater than 10%, for the three and nine months ended September 30, 2022, the Company earned Mytesi revenue primarily from two specialty pharmacies located in the United States. For the three and nine months ended September 30, 2021, the Company earned Mytesi revenue primarily from two specialty pharmacies in the United States. Revenue earned from each as a percentage of total revenue is as follows:

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2022	2021	2022	2021
Customer 1	— %	63 %	— %	79 %
Customer 2	38 %	17 %	35 %	12 %
Customer 3	54 %	16 %	53 %	— %

On September 3, 2021, the Company ended its engagement with Cardinal Health as its exclusive title model customer for commercial sales and fully implemented its limited distribution Specialty Pharmacy model. Cardinal Health continues to provide third-party logistics services for Mytesi.

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. As of September 30, 2022 and December 31, 2021, the Company's significant customers and their related accounts receivable balance as a percentage of total accounts receivable were as follows:

	September 30, 2022 (unaudited)	December 31, 2021
Customer 1	— %	16 %
Customer 2	38 %	37 %
Customer 3	55 %	37 %

The Company is subject to concentration risk from its suppliers. The Company sources raw material used to produce the active pharmaceutical ingredient ("API") in Mytesi from two suppliers and is dependent on a single third-party contract manufacturer for the supply of API in Mytesi and a single third-party contract manufacturer as well for the supply of finished products for commercialization.

Other Risks and Uncertainties

The Company's future results of 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 include, but are not limited to war, rapid technological change, obtaining second source suppliers, regulatory approval from the 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.

Recent Global Events

Macroeconomic conditions, including the war in Ukraine and related sanctions, exchange rate and interest rate volatility, and inflationary pressures, will continue to evolve globally. The greatest impact was a decline in Europe where the impacts of foreign currency exchange rates, the war in Ukraine, and energy inflation were the greatest. The Company's partially-owned subsidiary in Italy, Napo Thera, does not generate any revenue yet for the nine months period ending September 30, 2022. However, the Company expects that significant changes in the subsidiary's operations would be evident in the remainder of 2022 as a result of these recent global events.

Fair Value

The Company's financial instruments include accounts receivable, accounts payable, accrued liabilities, warrant liabilities, equity-linked financial instruments and debt. The recorded carrying amounts of accounts 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 either fair value or amortized cost using the effective interest method. See Note 4 for the fair value measurements.

Fair Value Option

ASC 825-10, *Financial Instruments*, provides 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.

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 raw materials or API, including the sum of qualified expenditures and charges in bringing the inventory to its existing condition and location. 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 reduction 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 allowance for inventory obsolescence as of September 30, 2022, and December 31, 2021.

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 3 to 10 years.

Expenditures for repairs and maintenance of assets are charged to expense 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.

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 an impairment trigger has been met, 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 (which are measured based on the difference between the fair value and the carrying value of the asset) are treated as permanent reductions in the carrying amount of the assets (asset group). Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's long-lived assets were impaired. The Company's had no impairment of long-lived assets as of September 30, 2022, and December 31, 2021.

Indefinite-lived Intangible Assets

Acquired IPR&D are intangible assets acquired in the July 2017 Napo merger. Under ASC 805, 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 in the three and nine months ended September 30, 2022, and 2021.

Leases

The Company accounts for its leases in accordance with ASC 842, *Leases*.

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.

Operating Lease

The Company entered into a sublease agreement with Peacock Construction Inc. ("Peacock"), a California corporation, for office space located in San Francisco, California. The term of the sublease began on August 31, 2020, and expired on May 31, 2021. The rent under the sublease is $15,000 per month beginning October 1, 2020, which includes operating expenses and taxes. On October 1, 2020, the Company transitioned its operations from its existing premises to the sublease premises, which the Company expects will serve as its principal administrative headquarters. The Company elected not to apply the recognition requirements to short-term leases, and instead recognize the lease payments in profit or loss on a straight-line basis over the lease term. As a result, there was no right-of-use asset and lease liability recognized related to the sublease.

In April 2021, the Company entered into an office lease agreement with M & E, LLC, a California Limited Liability Company, to lease approximately 10,526 square feet of office space located in San Francisco, California, inclusive of office space currently covered under the sublease agreement with Peacock. The term of the lease began on September 1, 2021, and will expire on February 28, 2025 unless earlier terminated. The base rent under the lease will be $42,000 monthly for the first 12 months, $43,000 monthly for the next 12 months and $45,000 for the last twelve months.

In October 2021, the Company entered into an agreement with Copernico Centrale for the lease of office premises from November 1, 2021 to April 30, 2022, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €10,000 or approximately $10,500. If the contract is not terminated within 12 months, the lease amount will be increased in line with the index of relevant inflation at each annual expiration of the start date of the contract. On January 26, 2022, the lease agreement was amended whereby the term was extended by 20 months from May 1, 2022, to December 31, 2023. All other contract provisions remained the same.

In December 2021, the Company entered into an agreement with Arval Service Lease Italia SpA for the lease of two separate vehicles for 48 months expiring on November 30, 2025. Total monthly lease payment amounted to €2,000 or $2,100 payable in advance. The Company elected to include both the lease and non-lease components as a single component and account for it as a lease. The Company also paid a total deposit of €19,000 or approximately $20,000, exclusive of VAT. Early termination of the contracts requires the payment of specified amounts.

In January 2022, the Company entered into an agreement with Copernico Centrale for the lease of office premises from March 1, 2022, to December 31, 2023, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €4,000 or approximately $4,200. A similar agreement was entered with the lessor for the lease of premises to be used as office space from November 1, 2022, to December 31, 2023, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €3,817 or approximately $4,000. If the contracts are not terminated within 12 months, the lease amounts will be increased in line with the index of relevant inflation at each annual expiration of the start date of the contract.

In May 2022, the Company entered into an agreement with ALD Automative Italia S.r.l for the lease of one vehicle for 48 months expiring on April 30, 2026. Total monthly lease payment amounted to €833 or approximately $880 payable in advance. The Company elected to include both the lease and non-lease components as a single component and account for it as a lease. The Company also paid a total deposit of €21,000 or approximately $22,000, exclusive of VAT. Early termination of the contracts requires the payment of specified amounts.

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 expense is charged to operating expense in the period incurred.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses 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 product 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.

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 – Cardinal Health and Other Distributors

Effective January 16, 2019, the Company engaged Cardinal Health as its exclusive third-party logistics distribution agent for commercial sales of the Company's Mytesi product and to perform certain other services which include, without limitation, storage, distribution, returns, customer support, financial support, Electronic Data Interchange ("EDI") and system access support (the "Exclusive Distribution Agreement").

On September 3, 2021, the Company ended its engagement with Cardinal Health as its exclusive title model customer for commercial sales and fully implemented its limited distribution Specialty Pharmacy model. Cardinal Health continues to provide third-party logistics services for Mytesi.

The Company's Canalevia-CA1 and Neonorm products are primarily sold to distributors, who then sell the products to the end customers. Since 2021, the Company has entered into two distribution agreements with established distributors (Vedco and Durvet) to distribute the Company's animal health products in the United States. The distribution agreements and the related purchase orders together meet the contract existence criteria under ASC 606 10 25 1. 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.

Transaction price

For contracts with Cardinal Health and other distributors, the transaction price is the amount of consideration to 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 price

For contracts with Cardinal Health and other distributors, the entire transaction price is allocated to the single performance obligation contained in each contract.

Revenue recognition

For contracts with Cardinal Health and other distributors, a single performance obligation is satisfied at a point in time, upon the free on board ("FOB") terms of each contract 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 pharmacy. Net revenue from the sale of Mytesi were $3.1 million and $406,000 for the three months ended September 30, 2022, and 2021, respectively. Net revenue from the sale of Mytesi were $8.5 million and $1.8 million for the nine months ended September 30, 2022, and 2021.

Animal

The Company recognized Canalevia-CA1 product revenues were $12,000 and zero for the three months ended September 30, 2022, and 2021, respectively. Revenues from the sale of Canalevia-CA1 were $143,000 and zero for the nine months ended September 30, 2022, and 2021, respectively. Neonorm revenues of $5,000 and $15,000 for the three months ended September 30, 2022, and 2021, respectively. Revenues from the sale of Neonorm were $40,000 and $54,000 for the nine months ended September 30, 2022, and 2021, respectively. Revenues are recognized at a point in time upon shipment, which is when title and control is transferred to the buyer. Sales of Canalevia-CA1, Neonorm Calf and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances.

Contracts – Specialty Pharmacies

Effective October 1, 2020, the Company engaged a private company as an authorized specialty pharmacy provider of the Company's Mytesi product. Under the Specialty Product Distribution Agreement, the Company shall supply the products to the private company's specialty pharmacies, through a designated wholesaler, 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 ("NDCs") 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 the 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 Company's promise to transfer Mytesi to specialty pharmacies, based on specified payment and shipping terms as outlined in the agreements.

Transaction price

The transaction price is the amount of consideration to which 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 free on board ("FOB") terms of each contract when control, including title and all risks, has transferred to the customer.

Disaggregation of Product Revenue

Sales of Mytesi are recognized as revenue at a point in time when products are delivered to the specialty pharmacies. Net revenue from the sale of Mytesi to the specialty pharmacies were $2.9 million and $209,000 for the three months ended September 30, 2022, and 2021, respectively. Net revenue from the sale of Mytesi to the specialty pharmacies were $7.5 million and $434,000 for the nine months ended September 30, 2022, and 2021, respectively.

Collaboration Revenue

Revenue recognition for collaboration agreements requires significant judgment. The Company's assessments and estimates are based on contractual terms, historical experience and general industry practice. Revisions in these values or estimations have the effect of increasing or decreasing collaboration revenue in the period of revision.

On September 24, 2018, the Company entered into a Distribution, License and Supply Agreement ("License Agreement") with Knight Therapeutics ("Knight"). 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 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, 2022, and 2021.

On June 21, 2022, the Company entered into a License Agreement ("License Agreement") with SynWorld Technology Corporation ("Synworld"). The License Agreement grants Synworld an exclusive, non-transferable, non-sublicensable license of patents and know-how to significantly improve and/or expand the scope of the Company's intellectual property rights and to commercialize a canine-specific pharmaceutical product that utilizes Crofelemer as its active drug substance marketed in the United States under the Trademark Canalevia®, Canalevia-CA1 and Canalevia CA-2 ("Product") for the treatment, prevention, or amelioration of diarrhea in dogs in China, excluding Hong Kong ("Licensee Territory"). Synworld is responsible to prepare, submit and obtain all regulatory approvals for the Product in the Licensee Territory on behalf of, and in the name of the Company (the "Services"). During the Initial Term, Synworld will be solely responsible for all fees and expenses incurred by or on behalf of Synworld with respect to the performance of the Services ("Regulatory Expense"), subject to both parties' election for the Company to reimburse Regulatory Expenses up to $2.0 million ("Reimbursement Cap"). All Regulatory Expenses in excess of the Reimbursement Cap and any additional fees and expenses incurred thereafter for maintaining the regulatory approvals will be borne by Synworld. As consideration for the license granted, Synworld should make non-refundable cash payments with an aggregate amount of $5.0 million during the initial two-year term of the agreement. The Company did not have any license revenues for the three and nine months ended September 30, 2022, and 2021.

Modifications to Liability-classified Instruments

In accounting for debt modifications and exchange transactions, it is the Company's policy to first determine whether it qualifies as a troubled debt restructuring ("TDR") pursuant to the guidance provided in ASC 470-60. A debt modification or exchange transaction that is not within the scope of the ASC 470-60 is accounted for under ASC 470-50 to determine if the transaction is a mere modification or an extinguishment.

For the nine months ended September 30, 2022, the Company entered into another amendment on the terms of its October 2020 and March 2021 Purchase Agreements (see Note 8).

Modifications to Equity-classified Instruments

In accounting for modifications of equity-classified warrants, it is the Company's policy to determine the impact by analogy to the share-based compensation guidance of ASC 718, *Compensation - Stock Compensation* ("ASC 718"). 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. 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 in the three and nine months ended September 30, 2022, and 2021.

In accounting for amendments to preferred stock, it is the Company's policy 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 and ASC 470-20. 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 preferred stock in the three and nine months ended September 30, 2022 and 2021.

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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company issues stock awards with only service-based vesting conditions, and records compensation expense for these awards using the straight-line method.

The Company uses the grant date fair market value of its common stock 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 restricted stock units ("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 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 Company'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 Company's common stock as reported on the date of the grant.

Foreign Currency Remeasurement and Translation

The functional currency of Napo Therapeutics is Euro. The Company follows ASC 830, *Foreign Currency Matters* ("ASC 830"). 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.

For certain subsidiaries, translation adjustments result from the process of 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 consolidated balance sheets as a component of accumulated other comprehensive loss.

Comprehensive Loss

For all periods presented, the comprehensive loss was equal to the net loss; therefore, a separate statement of comprehensive loss is not included in the accompanying unaudited condensed consolidated financial statements.

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the year by the weighted-average number of common shares 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 shares, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, because the impact of the potential dilutive shares of common stock would be anti-dilutive to

the calculation of net loss per common share. Diluted net loss per common share is the same as basic net loss per common share for the three and nine months ended September 30, 2022, and 2021.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company adopted the standard on January 1, 2022. The adoption of this standard did not have a material effect on the Company's unaudited condensed consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, *Issuer's Accounting for Certain Modification or Exchanges of Freestanding Equity-Classified Written Call Options* – a consensus of the FASB Emerging Issues Task Force. The ASU provides a principles-based framework to determine whether an issue should recognize the modification or exchange as an adjustment to equity or an expense. The Company adopted the standard on January 1, 2022. The adoption of this standard did not have a material effect on the Company's unaudited condensed consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. The standard also removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance to improve consistent application. The adoption of this standard did not have a material effect on the Company's unaudited condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): *Measurement of Credit Losses on Financial Instruments.* The main objective of the standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this standard replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The update is effective for the Company beginning January 1, 2023, with early adoption permitted. The Company is still evaluating the impact of the adoption of this standard.

3. Napo Therapeutics Subsidiary

As discussed in Note 1 – Organization and Business, Napo EU completed a merger with Dragon SPAC on November 3, 2021, with Dragon SPAC as the surviving entity. Dragon SPAC took over by operation of law all the assets, rights, reasons, and actions as well as liabilities, obligations, and commitments of Napo EU. The merged entity was named Napo Therapeutics. Napo Therapeutics now operates as a subsidiary of Napo, with Napo owning 99% of Napo Therapeutics' equity. This transaction was accounted for as a formation of a new subsidiary of the Company.

4. Fair Value Measurements

ASC 820, *Fair Value Measurements*, defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles 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 as follows:

- Level 1 – Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.
- Level 2 – 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.
- Level 3 – Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of the Company's financial instruments that were measured at fair value on a recurring basis as of September 30, 2022 and December 31, 2021.

	September 30, 2022			
(in thousands)	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ —	$ —
Streeterville note	—	—	7,167	7,167
Total fair value	$ —	$ —	$ 7,167	$ 7,167

	December 31, 2021			
(in thousands)	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 1	$ 1
Streeterville note	$ —	$ —	$ 7,818	$ 7,818
Total fair value	$ —	$ —	$ 7,819	$ 7,819

The change in the estimated fair value of Level 3 liabilities is summarized below:

	Nine Months Ended September 30, 2022	
(in thousands)	Warrant liability	Streeterville note
Beginning fair value of Level 3 liability	$ 1	$ 7,818
Additions	—	—
Exercises	—	—
Change in fair value	(1)	(651)
Ending fair value of Level 3 liability	$ —	$ 7,167

Warrant Liability

The warrants associated with the Level 3 warrant liability is the October 2018 Underwriter Warrants, which, at September 30, 2022, were valued at zero in the Company's unaudited condensed consolidated balance sheet. The warrants associated with the Level 3 warrant liability were the November 2016 Series A Warrants and the October 2018 Underwriter Warrants, which, at December 31, 2021, were valued at zero and $1,000, respectively, in the Company's unaudited condensed consolidated balance sheet.

The October 2018 Underwriter Warrants

The October 2018 Underwriter Warrants valuation of zero at September 30, 2022 was computed using the Black-Scholes-Merton pricing model using a stock price of $0.16, a strike price of $158 per share, an expected term of 1.01 years, volatility of 307% and a risk-free discount rate of 4.05%. The October 2018 Underwriter Warrants valuation of $1,000 at December 31, 2021 was computed using the Black-Scholes-Merton pricing model using a stock price of $1.04, a strike price of $158 per share, an expected term of 1.75 years, volatility of 180% and a risk-free discount rate of 0.65%. The change in the fair value of the warrants for the three and nine months ended September 30, 2022 was $1,000.

The November 2016 Series A Warrants

Series A Warrants has expired on May 29, 2022. The Series A warrant valuation of zero at December 31, 2021 was computed using the Black-Scholes-Merton pricing model using a stock price of $1.04, a strike price of $2,363 per share, an expected term of 0.41 years, volatility of 89% and a risk-free discount rate of 0.19%. The change in fair value of the warrants for the three and nine months ended September 30, 2022 was zero.

The May 2020 Series 3 Warrants

There were no outstanding May 2020 Series 3 Warrants as of September 30, 2022 and December 31, 2021. For the year ended December 31, 2021, certain holders of the Series 3 Warrants agreed to exercise total of 206,915 shares for a 1-for-1 exchange of common shares in an Alternate Cashless Exercise. The aggregate fair value of the common stock issued upon the exercise of the Series 3 Warrants as of the exercise date was $1.8 million.

Streeterville Note

The fair value of the Streeterville Note at January 13, 2021, date of issuance and as of September 30, 2022 amounting to $6.0 million and $7.2 million, respectively, were based on the weighted average discounted expected future cash flows representing the terms of the note, discounting them to their present value equivalents. This was classified as Level 3 fair values in the fair value hierarchy due to the use of unobservable inputs, including the Company's own credit risk.

The Company determined and performed the valuations of the Streeterville Note with the assistance of an independent valuation service provider. On a quarterly basis, the Company considers the main Level 3 inputs used derived as follows:

- Discount rate for the Streeterville note which was determined using a comparison of various effective yields on bonds as of the valuation date
- Market indications for vouchers, which affect the Return Bonus from the sale of Tropical Disease Priority Review Voucher ("TDPRV")
- Weighted probability of cash outflows which was estimated based on the entity's knowledge of the business and how the current economic environment is likely to impact the timing of the cash outflows, attributed to the different repayment features of the note

The following table summarizes the quantitative information about the significant unobservable inputs used in Level 3 fair value measurement:

Unobservable Inputs	Range of Inputs (probability-weighted average) 2022	2021	Relationship of unobservable inputs to fair value
Risk Adjusted Discount Rate	12.81%-27.34% (27.34%)	6.78% - 21.31% (21.31%)	If discount rate is adjusted to total of additional 100 basis points (bps), fair value would have decreased by $262,000. If discount rate is adjusted to total deduction of 100 bps, fair value would have increased by $262,000.
Sales Proceeds: Amount of comparable TDPRV	$67.5 million to $350 million ($100 million)	$67.5 million to $350.0 million ($100.0 million)	If expected cash flows by Management considered the lowest amount of market indications for vouchers, FV would have decreased by $825,000. If expected cash flows by Management considered the highest amount of market indications for vouchers, FV would have increased by $6.35 million.
Range of Probability for Timing of Cash Flows: Variations of the terms and conditions of the timing of cash flows, including settlement of the note principal, interest, penalties, and acceleration clause.	0.39%-41.88%	0.35%-46.06%	If expected cash flows by Management considered the Scenario with the least amount of indicated value, FV would have decreased by $705,000. If expected cash flows by Management considered the scenario with the greatest amount of indicated value, FV would have increased by $2.76 million.

Fair Value Option

Beginning January 1, 2021, the Company elected to apply the FVO accounting to selected financial instruments to align the measurement attributes of those instruments under U.S. GAAP and to simplify the accounting model applied to those financial instruments. The Company elected to apply FVO accounting to the entire class of hybrid instruments, including structured notes, of which there are assessed embedded derivatives that would be eligible for bifurcation. Changes in the fair value of FVO assets and liabilities as well as the mark-to-market adjustment on the entire class of hybrid instruments, including derivatives and the net realized gains or losses on these instruments are reported in the change in fair value of financial instruments in the unaudited condensed consolidated statements of operations.

As of September 30, 2022, the Company did not note any fair value movement on FVO liabilities attributable to any instrument-specific credit risk, which is recorded in other comprehensive loss.

Hybrid Instruments

The Company elected to apply FVO accounting to all of the hybrid instruments issued, including structured notes. The valuation of the hybrid instruments is predominantly driven by the derivative features embedded within the instruments. The Company determined and performed the valuations of the hybrid instruments with the assistance of an independent valuation service provider. The valuation methodology utilized is consistent with the income approach for estimating the fair value of the interest-bearing portion of the instrument and the related derivatives. Cash flows of the hybrid instruments in their entirety, including the embedded derivatives, are discounted at an appropriate rate for the applicable duration of the instrument. Interest on the interest-bearing portion of the instrument that is held to maturity is aggregated as gain (loss) on instruments designated at fair value and related derivatives in the change in fair value of

financial instruments and hybrid instruments designated at FVO of the unaudited condensed consolidated statements of operations.

The following table summarizes the fair value and unpaid principal balance for items the Company accounts for under FVO:

(in thousands)	Fair value	Unpaid Principal Balance	Fair Value Over (Under) Unpaid Principal Balance
At September 30, 2022			
Hybrid Instrument:			
Streeterville note	$ 7,167	$ 6,221	$ 946

5. Balance Sheet Components

Inventory

Inventory at September 30, 2022 and December 31, 2021 consisted of the following:

(in thousands)	September 30, 2022 (unaudited)	December 31, 2021
Raw Material	$ 2,014	$ 1,248
Work in Process	3,058	2,760
Finished Goods	1,529	892
Inventory	$ 6,601	$ 4,900

Property and Equipment, net

Property and equipment at September 30, 2022 and December 31, 2021 consisted of the following:

(in thousands)	September 30, 2022 (unaudited)	December 31, 2021
Land	$ 396	$ 396
Lab equipment	477	403
Clinical equipment	65	65
Software	63	63
Furniture and fixtures	18	14
Computers and peripherals	7	7
Total property and equipment at cost	1,026	948
Accumulated depreciation	(454)	(298)
Property and equipment, net	$ 572	$ 650

Depreciation and amortization expense was $15,000 and $156,000 for the three and nine months ended September 30, 2022, respectively. Depreciation and amortization expense was $8,000 and $25,000 in the three and nine months ended September 30, 2021, respectively.

Intangible Assets, net

Intangible assets at September 30, 2022 and December 31, 2021 consisted of the following:

(in thousands)	September 30, 2022 (unaudited)	December 31, 2021
Developed technology	$ 25,000	$ 25,000
Accumulated developed technology amortization	(8,611)	(7,361)
Developed technology, net	16,389	17,639
In-process research and development	4,800	4,800
In process research and development, net	4,800	4,800
Trademarks	300	300
Accumulated trademark amortization	(103)	(88)
Trademarks, net	197	212
Internal use software costs - registry	1,236	—
Accumulated internal use software costs amortization	(61)	—
Internal use software costs - registry, net	1,175	—
Total intangible assets, net	$ 22,561	$ 22,651

Amortization expense of finite-lived intangible assets was $483,000 and $1.3 million for the three and nine months ended September 30, 2022, respectively. Amortization expense was $422,000 and $1.3 million for the three and nine months ended September 30, 2021, respectively.

The Company's internal use software pertains to the capitalized development costs incurred to create a national canine cancer registry and cancer care index. Development costs includes external direct costs of materials and services consumed and fees paid to develop the software by a third-party provider.

The following table summarized the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2022:

(in thousands)	Amounts
Remainder of 2022	$ 484
2023	1,934
2024	1,934
2025	1,934
2026	1,934
Thereafter	9,541
	$ 17,761

6. Related Party Transactions

BOD Cash Compensation

Effective May 2021, the Company's BOD received cash compensation based on the Director Compensation Program for 2021 which will be paid quarterly. For the nine months ended September 30, 2022, and 2021, Company paid approximately $172,187 and $35,000 cash compensation to its directors, respectively.

7. Commitments and Contingencies

Commitments

Leases

August 31, 2020, the Company entered into an office sublease of approximately 5,263 square feet of office space in San Francisco. The term of the sublease expired on May 31, 2021. The rent sublease is $15,000 per month beginning on October 1, 2020, which includes operating expenses and taxes. The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense, included in general and administrative expenses in the unaudited condensed consolidated statements of operations, was zero and $60,000 for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, there were no remaining commitment under the lease.

On April 6, 2021, the Company entered into an office lease agreement of approximately 10,526 square feet of office space in San Francisco, inclusive of office space covered under the previous sublease agreement. The term of the lease began on September 1, 2021 and will expire on February 28, 2025, unless terminated earlier. The lease had an early occupancy provision which entitled the Company to use a portion of the leased premises on June 1, 2021, free of rent obligation. In addition, the Company has the option to extend the lease for one three-year period after the expiration date. This option was not included as part of the lease term as the Company was not reasonably certain to exercise it, hence the lease term only includes the noncancellable period of three years plus the period of early occupancy.

The base rent under the lease were $42,000 monthly for the first 12 months, $43,000 monthly for the next 12 months and $45,000 for the last twelve months. The lease agreement only contained one lease component, that is, the lease of the office space. Non-lease components such as payment of building operating costs and share in real property taxes were accounted for separately and were not considered as part of the total lease payments. The lease was classified as an operating lease.

On October 7, 2021, the Company entered into an agreement for the lease of office premises from November 1, 2021 to April 30, 2022, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €10,000 or approximately $10,500. If the contract is not terminated within 12 months, the lease amount will be increased in line with the index of relevant inflation at each annual expiration of the start date of the contract. The lessor has the right to decline the renewal of the contract. Upon the happening of certain specified events, the lessor may immediately withdraw from the contract. The Company is required leave the occupied spaces immediately in the same condition in which they were found in the event of contract termination or expiry. The Company paid deposit of €20,000 or approximately $21,000 to the lessor. On January 26, 2022, the lease agreement was amended whereby the term was extended by 20 months from May 1, 2022 to December 31, 2023. All other contract provisions remained the same.

On December 22, 2021, the Company entered into an agreement for the lease of two separate vehicles for 48 months expiring on November 30, 2025. Total monthly lease payment amounted to €2,000 or approximately $2,100 payable in advance. The Company elected to include both the lease and non-lease components as a single component and account for it as a lease. The Company also paid a total deposit of €19,000 or approximately $20,000, exclusive of VAT. Early termination of the contracts requires the payment of specified amounts.

On December 24, 2021, the Company entered into the first amendment of the lease of office space in San Francisco. The expiration of the lease was extended to February 28, 2025 due to the change in the commencement date of one of the leased premises to March 1, 2022. The base rent under the lease amendment remained the same but will only be due starting March 1, 2022. The rent in one of the leased premises currently being occupied by the Company was and will still be $21,000 until the new commencement date. The lease amendment constituted a lease modification where the Company remeasured the original lease liability using a discount rate determined at the effective date of the modification and the amount of remeasurement of the lease liability was recognized as an adjustment to the corresponding right-of-use asset without affecting profit or loss.

On January 25, 2022, the Company entered into an agreement for the lease of office premises from March 1, 2022 to December 31, 2023, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €4,000 or approximately $4,200. A similar agreement was entered with the lessor for the lease of premises to be used as office space from November 1, 2022 to December 31, 2023, subject to automatic renewal for subsequent periods until terminated by either party. Base rent amounted to €3,817 or approximately $4,000. If the contracts are not terminated within 12 months, the lease amounts will be increased in line with the index of relevant inflation at each annual expiration of the start date of the contract. The lessor has the right to decline the renewal of the contracts. Upon the happening of certain specified events, the lessor may immediately withdraw from the contracts. The Company is required leave the occupied spaces immediately in the same conditions in which they were found in the event of contract termination or expiry. The Company paid deposit of €9,000 or approximately $9,500 to the Lessor.

In May 2022, the Company entered into an agreement for the lease of one vehicle for 48 months expiring on April 30, 2026. Total monthly lease payment amounted to €833 or approximately $880 payable in advance. The Company elected to include both the lease and non-lease components as a single component and account for it as a lease. The Company also paid a total deposit of €21,000 or approximately $22,000, exclusive of VAT. Early termination of the contracts requires the payment of specified amounts.

The table below provided additional details of the office space lease presented in the condensed consolidated balance sheet as of September 30, 2022 and December 31, 2021:

(in thousands)	September 30, 2022 (unaudited)	December 31 2021
Operating lease - right-of-use asset	$ 1,104	$ 1,084
Operating lease liability, current	418	240
Operating lease liability, net of current portion	738	919
Total	$ 1,156	$ 1,159
Weighted-average remaining life (years)	2.08	3.21
Weighted-average discount rate	18.52%	21.10%

For the nine months ended September 30, 2022, and 2021, cash paid for operating lease liabilities recognized under operating cash flows amounted to $384,000 and $0 respectively.

The following table summarizes the undiscounted cash payment obligations for the operating lease liability as of September 30, 2022 and December 31, 2021:

(in thousands)	September 30, 2022 (unaudited)	December 31 2021
2022	146	463
2023	601	518
2024	565	534
2025	121	89
2026	3	—
Total undiscounted operating lease payments	1,436	1,604
Imputed interest expenses	(280)	(445)
Total operating lease liability	1,156	1,159
Less: Operating lease liability, current	418	240
Operating lease liability, net of current portion	$ 738	$ 919

On October 10, 2021, the Company also entered into a short-term office lease in Milan, Italy. The term of the lease began on November 1, 2021, subject to automatic renewal equal to the present term until terminated by mutual agreement. On January 26, 2022, the lease agreement was amended whereby the term was extended by 20 months from May 1, 2022 to December 31, 2023. The Company recognizes rent expense on a straight-line basis over the non-cancellable lease period.

Rent and lease expense included in the general and administrative expenses in the unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2022 was approximately $45,000 and $341,000, respectively. Accordingly, rent and lease expense for the three and nine months ended September 30, 2021 was approximately $103,000 and $123,000, respectively.

Purchase Commitment

On September 3, 2020, the Company entered into a manufacturing and supply agreement (the "Agreement") with Glenmark Life Sciences Limited ("Glenmark"), pursuant to which Glenmark will continue to serve as the Company's manufacturer of crofelemer for use in Mytesi, the Company's human prescription drug product approved by the U.S. Food and Drug Administration, and for other crofelemer-based products manufactured by the Company or its affiliates for human or animal use. The term of the Agreement is approximately 2.5 years (i.e., until March 31, 2023) and may be extended for successive two-year renewal terms upon mutual agreement between the parties thereto. Pursuant to the terms of the Agreement, Glenmark will supply crofelemer to the Company. The Agreement contains provisions regarding the rights and responsibilities of the parties with respect to manufacturing specifications, forecasting and ordering, delivery arrangements, payment terms, confidentiality and indemnification, as well as other customary provisions. The Agreement includes a commitment for the purchase from Glenmark of a minimum quantity of 300 kilograms of crofelemer per year, pro-rated for partial years, where the Company may be obligated to pay any shortfall. Either party may terminate the Agreement for any reason with 12 months prior written notice to the other party. In addition, either party may terminate the Agreement upon written notice as a result of a material breach of the Agreement that remains uncured for a period of 90 days. If the Company terminates the Agreement as a result of a material breach caused by Glenmark, the Company will not be obligated to pay for any minimum quantity shortfall. As of September 30, 2022, the remaining commitment is 149 kilograms.

Master Services Agreement ("MSA")

On October 5, 2020, the Company entered into another MSA for clinical research organization services (the "2020 MSA") and a service order under such 2020 MSA with Integrium. The service order covers the Company's planned upcoming pivotal Phase 3 clinical trial for cancer-therapy related diarrhea. As consideration for its services, the

Company will pay Integrium a total amount of up to approximately $12.4 million, later reduced to approximately $6.0 million, that will be paid over the term of the engagement and based on the achievement of certain milestones. The 2020 MSA will terminate upon the satisfactory performance of all services to be provided thereunder unless earlier terminated by the parties. For the nine months ended September 30, 2022, and 2021, the Company paid Integrium $1.0 million and $972,000, respectively, under the MSA.

Asset Transfer and Transition Commitment

On September 25, 2017, the Company entered into the Termination, Asset Transfer and Transition Agreement dated September 22, 2017 with Glenmark. As a result of the agreement, the Company now controls commercial rights for Mytesi for all indications, territories and patient populations globally, and also holds commercial rights to the existing regulatory approvals for crofelemer in Brazil, Ecuador, Zimbabwe and Botswana. In exchange, the Company agrees to pay Glenmark 25% of any payment it receives from a third party to whom the Company grants a license or sublicense or with whom the Company partners in respect of, or sells or otherwise transfers any of the transferred assets, subject to certain exclusions, until Glenmark has received a total of $7.0 million. For the nine months ended September 30, 2022, and 2021, the Company paid Glenmark $1.8 million and $1.9 million, respectively.

Revenue Sharing Commitment Update

On December 14, 2017, the Company announced its entry into a collaboration agreement with Seed Mena Businessmen Services LLC (“SEED”) for Equilevia™, the Company's non-prescription, personalized, premium product for total gut health in equine athletes. According to the terms of the Agreement, the Company will pay SEED 15% of total revenue generated from any clients or partners introduced to the Company by SEED in the form of fees, commissions, payments or revenue received by the Company or its business associates or partners, and the agreed-upon revenue percentage increases to 20% after the first million dollars of revenue. In return, SEED will provide the Company access to its existing United Arab Emirates (“UAE”) network and contacts and assist the Company with any legal or financial requirements. The agreement became effective on December 13, 2017 and will continue indefinitely until terminated by either party pursuant to the terms of the Agreement. No payments have been made to date.

Legal Proceedings

On July 20, 2017, a putative class action complaint was filed in the United States District Court, Northern District of California, Civil Action No. 3:17 cv 04102, by Tony Plant (the “Plaintiff”).

The Company answered the complaint on August 2, 2019; the answer denied the material allegations of the second amended complaint. Following the completion of document discovery, the parties engaged in a mediation that resulted in an agreement in principle to settle the litigation on a class-wide basis for $2.6 million.

On May 27, 2021, the court gave the final approval to the proposed settlement and the entire settlement consideration will be provided by the Company’s director and officer liability insurance carrier. Under the loss recovery model in ASC 450 and in reference to ASC 410, the ultimate net income effect of the recognized loss and the insurance proceeds directly related to the recognized loss is zero.

Contingencies

From time to time, the Company maybe a party to various legal actions, both inside and outside the U.S., arising in the ordinary course of its business or otherwise. The Company accrues amounts, to the extent they can be reasonably estimated, that the Company believes will result in a probable loss (including, among other things, probable settlement value), to adequately address any liabilities related to legal proceedings and other loss contingencies. A loss or a range of loss is disclosed when it is reasonably possible that a material loss will incur and can be estimated, or when it is reasonably possible that the amount of a loss, when material, will exceed the recorded provision. The Company did not have any material accruals for any currently active legal action in its consolidated balance sheets as of September 30, 2022, as the Company could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

8. Debt

Notes payable at September 30, 2022 and December 31, 2021 consisted of the following:

(in thousands)	September 30, 2022 (unaudited)	December 31, 2021
Royalty Interest	$ 39,646	$ 37,000
Streeterville Note	7,167	7,818
Insurance Financing	432	335
Tempesta Note	250	350
	47,495	45,503
Less: unamortized discount and debt issuance costs	(15,752)	(17,297)
Note payable, net of discount	$ 31,743	$ 28,206
Notes payable - non-current, net	$ 20,006	$ 25,022
Notes payable - current, net	$ 11,737	$ 3,184

Future maturities of the notes payable not designated at FVO as of September 30, 2022 are as follows:

(in thousands)	Amounts
As of September 30,	
2023	$ 11,737
2024	24,076
2025	4,515
2026	—
2027	—
	40,328
Less: unamortized discount and debt issuance costs	(15,752)
Total	$ 24,576

Future maturities are based on contractual minimum payments. Timing of maturities may fluctuate based on future revenue.

Sale of Future Royalty Interest

October 2020 Purchase Agreement

On October 8, 2020, the Company entered into another royalty interest purchase agreement (the "October 2020 Purchase Agreement") with Iliad, pursuant to which the Company sold to Iliad a royalty interest entitling Iliad to receive $12.0 million of future royalties on sales of Mytesi and certain up-front license fees and milestone payments from licensees and/or distributors (the "Royalty Repayment Amount") for an aggregate purchase price of $6.0 million.

Until such time as the Royalty Repayment Amount has been paid in full, the Company will pay Iliad 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/or distributors, but specifically excluding licensing fees and/or milestone payments that are reimbursements of clinical trial expenses (the "Royalty Payments"). Beginning on the six-month anniversary of the delivery of the October 2020 Purchase Agreement to the Company (the "Purchase Price Date") and continuing until the 12-month anniversary of the Purchase Price Date, the monthly Royalty Payment shall be the greater of (a) $250,000, and (b) the actual Royalty Payment amount Iliad is entitled to for such month. Beginning on the 12-month anniversary of the Purchase Price Date and continuing until 18-month anniversary of the Purchase Price Date, the monthly Royalty Payment shall be the greater of (a) $400,000 and (b) the actual Royalty Payment amount Iliad is entitled to for such month. Beginning on the 18-month anniversary of the Purchase Price Date and continuing until 24-month anniversary of the Purchase Price Date, the monthly Royalty Payment shall be the greater of (a) $600,000 and (b)

the actual Royalty Payment amount Iliad is entitled to for such month. Beginning on the 24-month anniversary of the Purchase Price Date and continuing until the Royalty Repayment Amount has been paid in full, the monthly Royalty Payment shall be the greater of (a) $750,000, and (b) the actual Royalty Payment amount Iliad is entitled to for such month.

The Royalty Interest amount of $12.0 million was classified as debt, net of a $6.0 million discount, at initial recognition. Under ASC 470-10-35-3, royalty payments to Iliad will be amortized under the interest method per ASC 835-30. Because there is no set interest rate, and because 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 34.51%.

Pursuant to the October 2020 Purchase Agreement, if the weekly volume weighted average price ("VWAP") of the Company's common stock is not equal or greater than the minimum VWAP of $0.9105 at least twice during each calendar month during the six-month period beginning on November 1, 2020, then the Royalty Repayment Amount will be automatically increased by $6.0 million at the end of such six-month period. During the observation period starting November 1, 2020, the Company's weekly VWAP failed to reach the minimum VWAP of $0.9105 and on November 13, 2020, the Company concluded that the contingent clause has been met, warranting an additional $6.0 million Royalty Repayment Amount, to be added to the outstanding balance commencing on May 10, 2021 for the purpose of cash interest calculation. The change in the Royalty Repayment Amount was accounted for as a debt modification and resulted in a new discount rate of 45.42%.

On April 13, 2021, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $3.0 million from the original outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 588,235 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares. The exchange agreement was accounted for as a modification and resulted in a new discount rate of 77.09%.

On February 11, 2022, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $2.4 million from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 1,733,750 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

On March 2, 2022, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $1.1 million from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 2,425,000 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

On March 4, 2022, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $800,000 from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 2,000,000 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

On March 9, 2022, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $700,000 from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 1,850,000 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

Because the period between the first and last exchanges occurred within a 12-month period and each was individually assessed as a modification, the debt terms that existed prior to the February 13 exchange was used in the application of the 10% test on the cumulative assessment performed. The exchanges were cumulatively accounted for as an extinguishment and resulted to a loss of $2.2 million.

On April 14, 2022, the Company entered into amendments (the "Royalty Interest Global Amendments") to its existing royalty interests including the Royalty Interest in the original principal amount of $12.0 million under the October 2020 Royalty Interest. The amendment grants the Company at its sole discretion, the right to exchange from time to time, all or any portion of the Royalty Interests 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. Under the Royalty Interest Global Amendments, the Company's ability to exchange the Royalty Interests for shares of the Company's common stock is subject to certain limitations, on which the Company will not have such right and issue any common stock to investors if (a) the issuance of the Company's common shares would cause investor's beneficial ownership to exceed 4.99% of Company's issued and outstanding common stock as of such date; (b) any of the exchange conditions has not been satisfied as of the applicable exchange date; and (c) the total cumulative number of shares of the Company's common stock issued pursuant to the Royalty Interests would exceed the requirements of The Nasdaq Capital Market (including the rules related to the aggregation of offerings under Nasdaq Listing Rule 5635(d) if applicable) (the "Exchange Cap"), unless stockholder approval is obtained to issue more than the Exchange Cap. The Exchange Cap shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

On May 13, 2022, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition $400,000 from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 1,143,643 shares of the Company's common stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

On July 25, 2022, the Company entered into another exchange agreement with Iliad, pursuant to which the parties agreed to partition $750,000 from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 2,365,930 shares of the Company's stock. The exchange consisted of Iliad surrendering the partitioned royalty in exchange for the exchange shares.

Although there were exchanges that occurred within the 12-month period prior to the May 13, 2022 and July 25, 2022 exchanges, these were previously accounted for as extinguishment and, therefore, cumulative assessment was not anymore performed. The exchange agreement was accounted for as a modification. As of September 30, 2022, the forecasted future revenues changed which resulted to a new discount rate of 39.73%.

Interest expense for the three and nine months ended September 30, 2022 was $752,000 and $2.8 million, respectively. Interest expense for the three and nine months ended September 30, 2021 was $990,000 and $3.0 million, respectively. As of September 30, 2022 and December 31, 2021, the carrying value of the debt is $7.5 million and $6.3 million, respectively.

December 2020 Purchase Agreement

On December 22, 2020, the Company entered into a royalty interest purchase agreement (the "December 2020 Purchase Agreement") with Irving Park Capital, LLC ("Irving"), a company affiliated with CVP, pursuant to which the Company sold to Irving a royalty interest entitling Irving to receive $12.0 million of future royalties on sales of Mytesi and certain up-front license fees and milestone payments from licensees and/or distributors (the "Royalty Repayment Amount") for an aggregate purchase price of $6.0 million.

Until such time as the Royalty Repayment Amount has been paid in full, the Company will pay Irving 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/or distributors, but specifically excluding licensing fees and/or 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 Irving is entitled to for such month.

The Royalty Interest amount of $12.0 million is classified as debt, net of a $6.0 million discount, at initial recognition. Under ASC 470-10-35-3, royalty payments to Irving will be amortized under the interest method per ASC

835-30. Because there is no set interest rate, and because 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%. As of September 30, 2022, the forecasted future revenues changed which resulted to a new discount rate of 29.55%.

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 $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.

Interest expense for the three and nine months ended September 30, 2022 was $1.0 million and $2.8 million, respectively. Interest expense for the three and nine months ended September 30, 2021 was $732,000 and $2.1 million, respectively. As of September 30, 2022 and December 31, 2021, the carrying value of the debt is $9.3 million and $7.6 million, respectively.

March 2021 Purchase Agreement

On March 8, 2021, the Company entered into a purchase agreement (the "March 2021 Purchase Agreement") with Streeterville Capital, LLC ("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. 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 Irving, 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.

The Royalty Interest amount of $10.0 million is classified as debt, net of a $5.0 million discount, at initial recognition. 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 because 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%.

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.

On August 17, 2022, the Company entered into an exchange agreement (the "Royalty Interest Exchange Agreement") with Streeterville to (i) partition a new royalty interest in the royalty repayment amount of $3.4 million ("Partitioned Royalty") from the royalty interest of the March 2021 Purchase Agreement and then cause the outstanding balance of the royalty interest to be reduced by an amount equal to the initial outstanding balance of the Partitioned Royalty, and (ii) exchange ("Royalty Exchange") the Partitioned Royalty for 11,500,000 million 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. Under the terms of the Royalty Interest Exchange Agreement, the Royalty Exchange will consist of Streeterville surrendering the Partitioned Royalty in exchange for the shares, free of any restrictive securities legend, and Streeterville shall give no consideration of any kind whatsoever to the Company in connection with the Royalty Interest Exchange Agreement.

On September 30, 2022, the Company entered into an exchange agreement with Streeterville, pursuant to which the parties agreed to partition $2.0 million from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 11,764,705 shares of the Company's common stock. The exchange consisted of Streeterville surrendering the partitioned royalty in exchange for the exchange shares. The exchange was accounted for as a debt modification and resulted to a reduction in the outstanding balance of the royalty interest amounting to $2.0 million. As of September 30, 2022, the forecasted future revenues changed which resulted to a new discount of 42.0%.

Interest expense for the three and nine months ended September 30, 2022 was $409,000 and $1.4 million, respectively. Interest expense for the three and nine months ended September 30, 2021 was $391,000 and $827,000, respectively. As of September 30, 2022 and December 31, 2022, the carrying value of the debt is $2.8 million and $5.8 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 to Streeterville (the entitling "Investor") a royalty interest to receive $12.0 million 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 on the basis of 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 of the Included Products from the Company to Napo EU S.p.A. and (3) 50% of royalties collected from licenses of the Included Products to third parties.

Pursuant to the terms of the 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%.

Interest expense for the three and nine months ended September 30, 2022 was $282,000. As of September 30, 2022, the carrying value of the debt is $4.2 million.

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 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 charge for each upcoming year to the outstanding balance on the date each such interest charge is accrued. The Company also paid $25,000 to cover legal fees, accounting costs, due diligence, monitoring and other transaction costs incurred in connection with the issuance of the note. The first year of prepaid interest and the transaction expenses are included in the original principal amount.

At any time following the occurrence of a trial failure which refers to any of the following: (i) the Company abandons the clinical trial with NP-300 for an indication for the symptomatic relief of infectious diarrhea for cholera; (ii) the Company fails to start the Phase 1 clinical trial of NP-300 for the symptomatic relief of infectious diarrhea for cholera by July 1, 2022; or (iii) the Company fails to meet all primary endpoints in the pivotal trials of NP-300 for the symptomatic relief if infectious diarrhea for cholera with statistical significance, Streeterville may elect to increase the outstanding balance as of the date of the trial failure by 25% without acceleration (the "Trial Failure Effect"). If Streeterville elects to apply the Trial Failure Effect, it reserves the right to declare the outstanding balance immediately due and payable at any time. As of September 30, 2022, no trial failure occurred.

Streeterville is entitled to a maximum of 18% and a minimum of 1% of the gross proceeds received by the Company from the sale of TDPRV (the "Return Bonus"). The Return Bonus percentage is reduced pro rata based on the percentage of the original principal balance of the note that has been repaid as of the date of the sale of the TDPRV. Even if the note has been paid in full at the time of the sale of the TDPRV, the Company is still obliged to pay Streeterville a Return Bonus of 1%. If Streeterville applies the Trial Failure Effect, the Return Bonus will automatically be reduced to 1%. If the TDPRV has not been sold as of the day immediately preceding the maturity date of the note, the Return Bonus percentage will be fixed as of such date. As of September 30, 2022, the Company has not sold any TDPRV.

Beginning on the earlier of (a) 6 months after January 2021, and (b) initiation of human trials with NP-300 for symptomatic relief of infectious diarrhea for cholera, the Company may pay all or any portion of the outstanding balance earlier than it is due. In the event the Company elects to prepay all or any portion of the outstanding balance, it shall pay to Streeterville 112.5% of the portion of the outstanding balance the Company elects to prepay. The Company may not prepay the note without the Streeterville's consent on the date the last patient is enrolled in a pivotal trial.

After Streeterville becomes aware of the occurrence of any default, Streeterville may accelerate the note, with the outstanding balance becoming immediately due and payable in cash at the Mandatory Default Amount (i.e., the outstanding balance following the application of the Default Effect). Streeterville reserves the right to declare the outstanding balance immediately due and payable at any time following the default. Default Effect means multiplying the outstanding balance as of the date of default by 5% or 15% for each occurrence of default, capped at an aggregate of 25%, and then adding the resulting product to the outstanding balance. The percentage to be used depends on whether the default is viewed as minor or major as defined in the agreement. Furthermore, interest accrues on the outstanding balance beginning on the date of default at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted under applicable law. As of September 30, 2022, no default has occurred.

In connection with the note issuance, the Company has entered into a security agreement with Streeterville, pursuant to which Streeterville will receive a first priority security interest in all existing and future NP-300 technology, and any TDPRV and the sale proceeds therefrom that may be granted to the Company by the FDA in connection with the development of NP-300 for the cholera indication. The Company also agreed, with certain exceptions, not to grant any lien on any of the collateral securing the note and not to grant any license under any of the intellectual property relating to such collateral. The grant of security interest has become effective upon the receipt of the Salix Waiver on April 6, 2021 in observance to the requirement of the settlement agreement previously entered by the Company with Salix Pharmaceuticals, Inc.

The Company irrevocably elected to initially and subsequently apply the FVO accounting to the entire note. The fair value at transaction date was equal to the cash proceeds received of $6.0 million. The transaction expense of $25,000 was recognized in profit and loss as incurred. The Company used the valuation report from an independent valuation service provided to measure the reporting date fair value of the note.

On April 14, 2022, the Company and Napo (together with the Company, the "Borrower"), entered into an amendment (the "Note Global Amendment") to the secured promissory note in the original principal amount of $6.2 million with Streeterville, pursuant to which the Borrower was granted the right to exchange from time to time at Borrower's sole discretion, all or any portion of the Note for shares of the Company's common stock at a price per share equal to the Exchange Price. Under the Note Global Amendment, the Borrower's ability to exchange the Note for shares of the Company's common stock is subject to certain limitations, including no exchange transaction to the extent the issuance of shares in such exchange would result in the total cumulative number of shares of the Company's common stock issued pursuant to the Note would exceed the Exchange Cap, unless stockholder approval is obtained to issue more than the Exchange Cap.

At September 30, 2022 and December 31, 2021, the fair value was determined to be $7.2 million and $7.8 million, respectively. For the three and nine months ended September 30, 2022, the net decrease in the fair value $175,000 and $651,000, respectively. For the three and nine months ended September 30, 2021, the net increase in the fair value was $569,000 and $1.5 million, respectively. The net increase or decrease is included in the change in fair value of financial instruments and hybrid instrument designated at FVO in the unaudited condensed consolidated statements of operations.

Insurance Financing

March 2021 First Insurance Financing

In March 2021, the Company entered into a premium finance agreement for $98,000 with First Insurance Funding ("First Insurance") representing the unpaid balance of the total premiums, taxes, and fees of $115,000 with an annual interest rate of 4.6%. The total finance charge was $2,000. Payment of principal and interest is due in equal monthly installments over ten months. The Company granted and assigned First Insurance a first priority lien on and security interest in the financed policies and any additional premium required under the financed policies. Interest expense for the three and nine months ended September 30, 2021 was zero and $2,000, respectively. The financing balance was zero and $10,000 at September 30, 2022 and December 31, 2021, respectively.

May 2021 First Insurance Financing

In May 2021, the Company entered into another premium finance agreement for $1.1 million with First Insurance representing the unpaid balance of the total premiums, taxes, and fees of $1.4 million with an annual interest rate of 4.15%. The total finance charge was $21,000. Payment of principal and interest is due in equal monthly installments over ten months. Interest expense for the three and nine months ended September 30, 2022 was $0 and $6,000, respectively. Interest expense for the three and nine months ended September 30, 2021 was $6,000 and $8,000, respectively. The financing balance was zero and $326,000 at September 30, 2022 and December 31, 2021, respectively.

May 2022 First Insurance Financing

In May 2022, the Company entered into another premium finance agreement for $752,000 with First Insurance representing the unpaid balance of the total premiums, taxes, and fees of $941,000 with an annual interest rate of 4.3%. The total finance charge was $15,000. Payment of principal and interest is due in equal monthly installments over ten months. Interest expense for the three and nine months ended September 30, 2022 was $6,000 and $8,000. The financing balance was $651,000 at September 30, 2022.

2019 Tempesta Note

In October 2019, the Company entered into a License Termination and Settlement Agreement with Dr. Michael Tempesta, pursuant to which certain royalty payment disputes between the Company and Tempesta were settled. Per the terms of the Agreement, Tempesta received $50,000 in cash, an unsecured promissory note issued by the Company in the aggregate principal amount of $550,000 and 13,333 shares of the Company's common stock in exchange for the cessation of all royalty payments by the Company to Dr. Tempesta under the License Agreements. The $550,000 promissory note bears interest at the rate of 2.5% per annum and matures on March 1, 2025. The promissory note provides for the Company to make semi-annual payments equal to $50,000 plus accrued interest beginning on March 1, 2020 until the Note is paid in full. Interest expense for the three and nine months ended September 30, 2022 was $3,000 and $10,000, respectively. Interest expense for the three and nine months ended September 30, 2021 was $3,000 and $8,000, respectively. At September 30, 2022 and December 31, 2021, the net carrying value of the note was $250,000 and $350,000, respectively.

Oasis Secured Borrowing

The Purchase Agreement

In May 2020, the Company, entered into a one-year Accounts Receivable Purchase Agreement (the "Purchase Agreement") with Oasis Capital ("Oasis").

In December 2020, the Company received cash proceeds of $1.6 million from Oasis (the "Tranche #6 Secured Note"). Oasis purchased accounts receivable with a carrying value of $2.2 million, or gross accounts receivable of $3.8 million net of chargebacks and discounts of $1.6 million.

In February 2021, the Company made its final required payment to Oasis under Tranche #6 Secured Note, with total payments equaling the $1.8 million Threshold amount plus the transaction fee, and the Tranche #6 Secured Note was extinguished.

Exchange Note 2

In May 2019, CVP and the Company agreed to exchange two Napo convertible notes for a single CVP Note ("Exchange Note 1"). Per agreement, in consideration of the extension of the maturity date of Exchange Note 1 from December 31, 2019 to December 31, 2020, the Company issued a note ("Exchange Note 2") with a principal balance of $2.3 million. The maturity date of Exchange Note 2 is December 31, 2020, with an interest rate of 10%. Between September 2020 and November 2020, the Company and CVP entered into a series of note exchange agreements pursuant to which the Company made prepayments of principal and related accrued interest of an aggregate amount of $5.0 million, in lieu of making cash payments to CVP on Exchange Note 1, by issuing a total of 6,740,573 shares of the Company's common stock to CVP. The series of exchanges was accounted for as an extinguishment which resulted in a loss of $560,000. As of December 31, 2020, the carrying value of Exchange Note 1 was zero.

In September 2020, the Company and CVP also entered into a global amendment agreement, pursuant to which the maturity date of Exchange Note 2 is extended to December 31, 2021. In consideration of CVP's grant of extension, together with the related fees and other accommodation set forth, principal debt was increased by 5% of the outstanding balance of Exchange Note 2, which was $2.6 million as of the global amendment date. The global amendment requires redemption of Series D Perpetual Preferred Stock prior to payment of principal of Exchange Note 2. The Company

determined the incremental value of cash flows amounting to $228,000 with the assistance of an independent valuation service provider, based on weighted probability assumptions of various settlement conditions and penalties stipulated in the contract therein. The global amendment agreement was accounted for as a modification; hence a new effective rate was determined at the date of modification that equated the revised cash flows to the carrying amount of the note.

Pursuant to the global amendment agreement, the Company issued 842,500 shares of Series D Perpetual Preferred Stock. The Series D Perpetual Preferred shares were redeemable upon the option or discretion of the Company. The Series D Perpetual Preferred stockholders were entitled to receive 8% cumulative stock dividends, to be payable in arrears on a monthly basis for 24 consecutive months. Dividends payable on the Series D perpetual preferred shares shall be payable through the Company's issuance of Series D Perpetual Preferred share by delivering to each record holder the calculated number of payment-in-kind ("PIK") dividend shares. The Series D Perpetual Preferred shares were classified as liability and were measured at fair value using the income approach, which considered the weighted probability of discounted cash flows at various scenarios of redemption and perpetual holding of the shares. The Company determined the fair value of $6.4 million at contract inception date with the assistance of an independent valuation service provider to be based on discounted cash flows representing the settlement value of the shares and cumulative dividends issued using an effective borrowing rate of 12% to 15% adjusted for counterparty and a maturity date of September 30, 2021. In consideration of the global amendment agreement, no principal payment shall be made to the Exchange Note 2 until the redemption of Series D Perpetual Preferred shares. Due to the restrictive nature of the timing of cash outflows in response to the settlement of the Exchange Note 2, Series D Perpetual Preferred shares were implicitly deemed to be mandatorily redeemable upon the ultimate settlement of the outstanding balance of Exchange Note 2. The shares were redeemable at $8.00 per share on or before December 31, 2024, the date in which contractual cash outflows of the Exchange Note 2 require the entire settlement or redemption of the Series D Perpetual Preferred shares. In December 2020, the Company entered into a series of exchange agreements with a stockholder pursuant to which the Company agreed to issue a total of 5,296,623 shares of common stock in exchange for redeeming 859,348 shares of Series D Perpetual Preferred Stock. The series of exchanges was accounted for as an extinguishment which resulted to a loss amounting to $1.3 million. This is included in loss on extinguishment of debt and conversion of Series D Perpetual Preferred Stock on the statement of operations as of December 31, 2020. As of September 30, 2022 and December 31, 2021, there were no Series D Perpetual Preferred shares outstanding.

In December 2020, the Company and CVP entered into a note exchange agreement to which the Company made a prepayment of principal amounting to $1.0 million, in lieu of making cash payments to CVP on Exchange Note 2, by issuing 416,666 shares of the Company's common stock to CVP on December 31, 2020. The exchange agreement was accounted for as a modification.

In January 2021, the Company and CVP entered into another note exchange agreement to which the Company made a prepayment of the remaining outstanding balance of Exchange Note 2 amounting to $1.8 million, in lieu of making cash payments to CVP by issuing 471,202 shares of the Company's common stock to CVP on January 4, 2021. The exchange was accounted for as debt extinguishment which resulted in a loss of $753,000.

9. Warrants

The following table summarizes information about warrants outstanding and exercisable into shares of the Company's common stock as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31 2021
Warrants outstanding, beginning balance	563,451	2,401,818
Issuances	—	168,750
Exercises	—	(2,007,117)
Expirations and cancelations	(604)	—
Warrants outstanding, ending balance	562,847	563,451

October 2018 Underwriter Warrants

In October 2018, the Company issued warrants to various service providers to purchase an aggregate of 5,713 shares of common stock at an exercise price of $157.50 per common share. The warrants were classified as liabilities pursuant to ASC 815-40 as there was potential cash settlement.

April 2020 Underwriter Warrants

In April 2020, in consideration of the settlement of a dispute regarding underwriting fees (see Note 7), the Company issued warrants to purchase 33,592 shares of common stock at an exercise price of $7.50 per common share. The warrants were equity classified in the unaudited condensed consolidated statements of changes in convertible preferred stock and stockholders' equity.

March 2019 Ladenburg Warrants

In March 2019, the Company issued warrants to purchase an aggregate of 253 shares of common stock at an exercise price of $52.50 per common share. The warrants were equity classified in the unaudited condensed consolidated statements of changes in convertible preferred stock and stockholders' equity.

March 2019 LOC Warrant

In March 2019, the Company issued a warrant to purchase warrant shares equal to a fixed principal amount divided by a variable exercise price. On July 23, 2019, upon the exercise price of the warrants becoming fixed, the warrants became exercisable into 15,250 shares of the Company's common stock and were reclassified to additional paid-in-capital.

2019 Bridge Note Warrants

Between March 18, 2019 and June 26, 2019, the Company issued twenty-one warrants to purchase warrant shares equal to a fixed principal amount divided by a variable exercise price. On July 23, 2019, upon the exercise price of the warrants becoming fixed, the warrants became exercisable into 927,083 shares of the Company's common stock and were reclassified to additional paid-in-capital with a strike price of $6.00 per share.

A total of 190,622 2019 Bridge Notes Warrants were outstanding as of September 30, 2022 and December 31, 2021 with a strike price of $1.47.

July 2019 Series 1 Warrants

In July 2019, the Company entered into an underwriting agreement, relating to a public offering, which was comprised of (1) 962,166 Class A Units, priced at $6.00 per unit, with each unit consisting of (i) one share of the Company's voting common stock, (ii) one Series 1 warrant to purchase one share of common stock, and (iii) one Series 2 warrant to purchase one share of common stock, and (2) 10,787 Class B Units, priced at a price of $1,000 per unit, with each unit consisting of (i) one share of Series B convertible preferred stock, convertible into 166 shares of common stock, (ii) 166 Series 1 Warrants and (iii) 166 Series 2 Warrants.

The Series 1 Warrants had an exercise price of $6.00 and expire on the earlier of (a) 5 years from the date of issuance and (b) 30 calendar days following the public announcement of Positive Interim Results related to the diarrhea results from the HALT-D investigator-initiated trial, if and only if certain trading benchmarks are achieved during such 30-calendar day period.

In the offering, the Company sold (i) 962,166 Class A Units, which included Series 1 warrants to purchase 962,166 shares of the Company's common stock and (ii) 10,787 Class B Units, which included Series 1 warrants to purchase 1,797,833 shares of the Company's common stock. In total, 2,760,000 Series 1 warrants were issued, with a strike price of $6.00. Upon issuance, the Series 1 warrants were classified in additional paid-in-capital.

During the three and nine months ended September 30, 2021, an aggregate of 464,058 shares of common stock were issued upon the exercise of the Series 1 Warrants for total proceeds of $682,000.

A total of 145,396 Series 1 Warrants were outstanding as of September 30, 2022 and December 31, 2021.

July 2019 Series 2 Warrants

The Series 2 Warrants have an exercise price of $6.00 and expire on the first date on the earlier of (a) 5 years from the date of issuance and (b) 30 calendar days following the public announcement by the Company that a pivotal phase 3 clinical trial using crofelemer (Mytesi, or the same or similar product with a different name) for the treatment of cancer therapy-related diarrhea in humans has met its primary endpoint in accordance with the protocol, if and only if certain trading benchmarks are achieved during such 30 calendar day period. In addition, each Series 2 Warrant has an embedded call option that allows the Company to redeem any unexercised warrants if certain contingencies are met.

In the July 2019 offering, the Company sold (i) 962,166 Class A Units, which included Series 2 warrants to purchase 962,166 shares of the Company's common stock and (ii) 10,787 Class B Units, which included Series 2 warrants to purchase 1,797,833 shares of the Company's common stock. In total, 2,760,000 Series 2 warrants were issued, with a strike price of $6.00, and an expected term of 5.0 years. Upon issuance, the Series 2 Warrants were classified in additional paid-in-capital.

During the three and nine months ended September 30, 2021 an aggregate of 1,797,833 shares of common stock were issued upon the exercise of the Series 2 Warrants for total proceeds of $5.0 million

A total of 133,730 Series 2 Warrants were outstanding as of September 30, 2022 and December 31, 2021.

April 2021 ELOC Warrants

On April 7, 2021, in consideration for Oasis Capital's entry into the March 2020 ELOC amendment, the Company issued Oasis Capital a common stock purchase warrant ("ELOC Warrants") exercisable for 33,333 shares of common stock with an exercise price per share equal to $5.61 on the date of the amendment. The warrants were valued at $172,000 using the Black-Scholes option pricing model as follows: exercise price of $5.61 per share, stock price of $5.61 per share, expected life of five years, volatility of 156%, and a risk-free rate of 0.87%. The warrants were classified in additional paid-in-capital.

10. Preferred Stock

At September 30, 2022 and December 31, 2021, preferred stock consisted of the following:

(in thousands, except share and per share data) Series	Shares Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference per Share
B-2	10,165	—	$ —	$ —
C	1,011,000	—	—	8.00
Total	1,021,165	—	$ —	

Series B-2 Convertible Preferred Stock

In December 2019, the Company entered into an exchange agreement with Oasis Capital, pursuant to which Oasis Capital gave up (i) its remaining unexercised Prepaid Forward contracts exercisable for 412,074 shares of the Company's common stock and (ii) 231,709 common shares held as an investment by Oasis Capital, in exchange for 10,165 shares of the Company's newly authorized Series B-2 Convertible Preferred Stock.

Holders of the Series B-2 Convertible Preferred Stock are entitled to receive dividends on shares of Series B-2 Convertible Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends

actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be paid on shares of the Series B-2 Convertible Preferred Stock.

The shares of Series B-2 Convertible Preferred Stock have no voting rights. However, as long as any shares of Series B-2 Convertible Preferred Stock remain outstanding, the Company shall not, without the affirmative vote of holders of a majority of the then outstanding shares of Series B-2 Convertible Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B-2 Convertible Preferred Stock or alter or amend the Series B-2 Certificate of Designation or (b) enter into any agreement with respect to any of the foregoing.

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Holders of the Series B-2 Convertible Preferred Stock were entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series B-2 Convertible Preferred Stock were fully converted to Common Stock which amounts shall be paid *pari passu* with all holders of common stock.

Each share of Series B-2 Convertible Preferred Stock is convertible at any time at the holder's option into 63 shares of Common Stock, as determined by dividing the $153.90 stated value of each Series B-2 Convertible Preferred Share by the $2.43 conversion price ($153.90 divided by $2.43 = 63 conversion ratio), and which conversion ratio is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations and other similar transactions as specified in the Series B-2 Certificate of Designation. The Series B-2 Convertible Preferred Stock was classified in stockholders' equity in accordance with authoritative guidance.

In January 2020, a holder of the Series B-2 Convertible Preferred Stock converted 2,631 preferred shares into 166,630 shares of common stock. In October 2020, the Company entered into an exchange agreement with Oasis Capital pursuant to which the Company agreed to issue 166,728 shares of common stock in exchange for 975 shares of the Series B-2 Convertible Preferred Stock. The exchange agreement was accounted for as a modification. In December 2020, an investor converted the remaining 6,559 Series B-2 Convertible Preferred Stock into a total of 415,403 shares of the Company's common stock.

As of September 30, 2022 and December 31, 2021, there were no Series B-2 Convertible Preferred shares outstanding.

Series C Perpetual Preferred Stock

In September 2020, the Company entered into an exchange agreement with Iliad to issue 842,500 shares of the Company's Series C Perpetual Preferred Stock at $0.0001 par value per share, for a non-cash exchange of equity instruments. The exchange agreement was contemporaneously entered with the issuance of Series D Perpetual Preferred shares, in exchange of remaining Series A Convertible Preferred shares totaling 5,524,926 shares, and accreted value of $11.2 million as of the exchange date. An amendment agreement of the Exchange Note 2 was also entered into, with issuance value of $2.3 million and carrying value of $2.6 million as of the exchange date, to extend maturity from December 31, 2020 to December 31, 2021, in consideration of 5% increase in the outstanding balance.

Holders of the Series C Perpetual Preferred Stock were not entitled to voting rights. However, as long as any Series C Perpetual Preferred share is outstanding, the Company is restricted to alter, change, or enter into an agreement to alter or change adversely the powers, preferences, or rights given to the shareholders.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or deemed liquidation event, the holders of Series C Perpetual Preferred shares then outstanding would be entitled to be paid in cash out of the assets of the Company before any payment shall be made to the holders of common stock or shares of any series or class of preferred or other capital stock then outstanding that by its terms is junior to the Series C Perpetual Preferred shares in respect of the preferences as to distributions and payments upon such liquidation event by reason of their ownership, an amount per share of Series C equal to one times the Series C original issue price.

The Series C Perpetual Preferred shares were redeemable upon the option or discretion of the Company.

The Series C Perpetual Preferred shares were entitled to receive 10% cumulative stock dividends, to be payable in arrears on a monthly basis for 24 consecutive months. Dividends payable on the Series C Perpetual Preferred shares shall be payable through the Company's issuance of Series C Perpetual Preferred share by delivering to each record holder the calculated number of PIK dividend shares.

The Series C Perpetual Preferred shares were initially measured at fair value using the income approach, which considered the weighted probability of discounted cash flows at various scenarios of redemption by the Company or liquidation event and perpetual holding of the shares. As of the date of exchange, total fair value of the Series C Perpetual Preferred shares amounted to $4.7 million. Subsequently, the carrying amount of Series C Perpetual Preferred shares increased as the PIK dividend shares were recognized.

The preferred stock has been classified as permanent stockholders' equity in accordance with authoritative guidance for the classification and measurement of perpetual shares without mandatory redemption period because the redemption option was ultimately in the control of the Company.

In October 2020, the Company entered into an exchange agreement with Iliad pursuant to which the Company agreed to issue a total of 83,333 shares of common stock and pre-funded warrants to purchase 2,352,563 shares of common stock in exchange for 285,000 shares of Series C Perpetual Preferred Stock. The pre-funded warrants were exercisable immediately and could be exercised at any time until all of the pre-funded warrants were exercised in full. The nominal exercise price of each pre-funded warrant was $0.0003. In December 2020, the Company also entered into a series of exchange agreements with Iliad pursuant to which the Company agreed to issue a total of 2,734,626 shares of common stock in exchange for 573,810 shares of Series C Perpetual Preferred Stock. The series of exchanges were viewed as singular transaction, hence combined for purposes of accounting for the subsequent amendments. The series of exchanges was accounted for as an extinguishment which resulted in a $2.5 million deemed dividend, recorded against additional paid-in capital, for the difference between the fair value of the shares of common stock and pre-funded warrants transferred and the carrying amount of the Series C Perpetual Preferred Stock. As of December 31, 2020, Iliad had exercised all pre-funded warrants for $1,000.

As of September 30, 2022 and December 31, 2021, there were no Series C Perpetual Preferred shares outstanding.

Series E Preferred Stock

On August, 2022, the Company entered into an agreement (the "Securities Purchase Agreement") with Synworld to issue 10 Series E Preferred Stock with a par value of $0.0001, amounting to $100. In consideration of the Securities Purchase Agreement, the Company and Synworld agree to amend the existing definition of the term "Service Share Amount" in the License Agreement entered by both parties (See Note 2) and include a subsection for lock-up wherein Synworld agrees not to sell, transfer, loan, grant any option of the purchase of, or otherwise dispose of any shares of common stock acquired pursuant to the License Agreement until after the 90-day period following the date of acquisition.

As of September 30, 2022 and December 31, 2021, there were ten and zero Series E Preferred shares outstanding, respectively.

On October 4, 2022, the Company redeemed all 10 shares of Series E Preferred Stock in accordance with the terms of such securities. As a result, no shares of Series E Preferred Stock remain outstanding.

11. Stockholders' Equity

As of September 30, 2022 and December 31, 2021, the Company had reserved shares of common stock, on an as-if converted basis, for issuance as follows:

	September 30, 2022	December 31, 2021
	(unaudited)	
Options issued and outstanding	2,319,071	2,464,803
Inducement options issued and outstanding	116,451	38,289
Options available for grant under stock option plans	694,615	631,270
Restricted stock unit awards issued and outstanding	3,381,176	487,456
Warrants issued and outstanding	562,847	563,451
Total	7,074,160	4,185,269

Common Stock

The holders of common stock are entitled to one vote for each share of common stock held. The common stockholders are also entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors.

The holders of non-voting common stock are not entitled to vote, except on an as converted basis with respect to any change of control of the Company that is submitted to the stockholders of the Company for approval. Shares of the Company's non-voting common stock have the same rights to dividends and other distributions and are convertible into shares of the Company's common stock on a one-for-one basis.

At a special meeting of stockholders of Jaguar Health, Inc. (the “Company”) held on September 30, 2022 (the “Special Meeting”), the Company’s stockholders approved an amendment (the “Sixth Amendment”) to the Company’s Third Amended and Restated Certificate of Incorporation (the “COI”) to effect an increase in the number of authorized shares of the Company’s voting common stock, par value $0.0001 per share (the “Common Stock”), from 150,000,000 to 298,000,000 shares of Common Stock (the “Authorized Share Increase”) on September 30, 2022.

Pursuant to such authority granted by the Company’s stockholders, the Company’s board of directors approved the Authorized Share Increase and the filing of the Sixth Amendment to effectuate the Authorized Share Increase. On September 30, 2022, the Company filed the Sixth Amendment with the Secretary of State of the State of Delaware (the “DE Secretary of State”), and the Authorized Share Increase became effective in accordance with the terms of the Sixth Amendment immediately upon filing with the DE Secretary of State (the “Effective Time”).

The Company is now authorized to issue a total number of 352,475,074 shares, of which 298,000,000 shares are common stock, 50,000,000 are non-voting common stock and 4,475,074 are preferred stock.

Reverse Stock Split

On September 3, 2021, the reverse stock split of the Company’s issued and outstanding voting common stock at a ratio not less than 1-for-2 and not greater than 1-for-20 became effective. Upon effectivity, every three shares of the Company’s issued and outstanding common stock immediately prior to the effective time shall automatically be reclassified into one share of common stock without any change in the par value. The reverse stock split reduces the number of shares of common stock issuable upon the conversion of the Company’s outstanding non-voting common stock and the exercise or vesting of its outstanding stock options and warrants in proportion to the ratio of the reverse stock split and causes a proportionate increase in the conversion and exercise prices of such non-voting common stock, stock options and warrants. In addition, the number of shares reserved for issuance under the Company’s equity compensation plans immediately prior to the effective time will be reduced proportionately. The reverse stock split did not change the total number of authorized shares of common stock or preferred stock.

March 2020 ELOC (Equity Line of Credit)

In March 2020, the Company entered into an equity purchase agreement (the "March 2020 ELOC") with Oasis Capital, which provides that Oasis Capital is committed to purchase up to an aggregate of $2.0 million shares of the Company's common stock over the 36-month term of the March 2020 ELOC.

Pursuant to the terms and conditions of the March 2020 ELOC, on any trading day selected by the Company (such date the "Put Date"), after the SEC has declared effective the registration statement registering the sale of the shares of common stock that may be issued to Oasis Capital under the March 2020 ELOC, the Company has the right, in its sole discretion, to present to Oasis Capital with a purchase notice (each a "Put Notice"), directing Oasis Capital to purchase up to the lesser of (i) 66,666 shares of common stock or (ii) 20% of the average trading volume of common stock in the 10 trading days immediately preceding the date of such Put Notice, at a per share price equal to $1.31 (each an "Option 1 Put"), provided that the aggregate of all Option 1 Puts and Option 2 Puts (described below) does not exceed $2.0 million.

In addition, on any date on which Oasis Capital receives shares of common stock in connection with a Put Notice (the "Clearing Date"), the Company also has the right, in its sole discretion, to present to Oasis Capital with a Put Notice (each an "Option 2 Put") directing Oasis Capital to purchase an amount of common stock equal to the lesser of (i) such amount that equals 10% of the daily trading volume of the common stock on the date of such Put Notice and (ii) $200,000, provided that the aggregate amount of the Option 1 Put and Option 2 Put on any Put Date or Clearing Date does not exceed $500,000 and the aggregate amount of all Option 1 Puts and Option 2 Puts does not exceed $2.0 million. The purchase price per share pursuant to such Option 2 Put is equal to $1.31. The threshold price and the purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the period used to compute the threshold price or the purchase price.

On April 15, 2020, the SEC declared effective the registration statement registering the sale of the shares of common stock issued to Oasis Capital under the March 2020 ELOC. The Company will control the timing and amount of sales of common stock to Oasis Capital. Oasis Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the March 2020 ELOC.

In connection with the equity line, the Company agreed to pay Oasis Capital a commitment fee and in April 2020, in settlement of the commitment fee, the Company issued to Oasis Capital 22,935 shares of common stock. At issuance, the 22,935 shares of common stock had a fair value of $33,027, and were expensed as an issuance cost in the Company's unaudited condensed consolidated statements of operations.

Per the terms of the equity purchase agreement, the Option Put 1 and Option Put 2 may be exercised only at a price that is always above the trading price of the underlying common stock at the exercise date, thereby rendering any exercise by the Company being out-of-the-money. At inception of the equity line on March 24, 2020, the Put Options were classified as derivative assets with a fair value of zero, and upon an effective registration statement on April 15, 2020, were reclassified to stockholders' equity with a fair value of zero.

In April 2020, the Company exercised a single Put Option Put 1 under which the Company sold 17,333 common shares to Oasis for gross proceeds of $22,627. As of September 30, 2022 and December 31, 2021, the Company had not exercised any further put options to require Oasis Capital to purchase common stock under the equity purchase agreement.

On April 7, 2021, the Company entered into an amendment to the March 2020 ELOC with Oasis Capital, pursuant to which the parties agreed to increase (i) the purchase price from $1.31 to $9.00 and (ii) the threshold price from $1.50 to $10.35. In consideration for Oasis Capital's entry into the amendment, the Company issued Oasis Capital a common stock purchase warrant ("ELOC Warrants") exercisable for 33,333 shares of common stock with an exercise price per share equal to $5.61 on the date of the amendment.

At the Market Offering ("ATM")

October 2020 ATM Agreement

On October 5, 2020, the Company entered into an ATM Agreement with Ladenburg, pursuant to which the Company may offer and sell, from time to time through Ladenburg, shares of common stock, subject to the terms and conditions of the ATM Agreement. The ATM Agreement will terminate upon the earlier of (i) October 5, 2022 and (ii) termination of the ATM Agreement as permitted therein. In 2020, the Company sold 1,271,639 shares of common stock under the ATM Agreement resulting in net proceeds of approximately $1.3 million after commissions and expenses of approximately $40,000.

In 2021, the Company issued an aggregate of 669,850 shares under the ATM Agreement for total net proceeds of $5.4 million after commissions and expenses of approximately $311,000.

As of September 30, 2022 and December 31, 2021, all shares under the ATM Agreement have been issued.

December 2021 ATM Agreement

On December 10, 2021, the Company entered into another ATM Agreement ("December 2021 ATM Agreement") with Ladenburg, pursuant to which the Company may offer and sell, from time to time through Ladenburg, shares of common stock having an aggregate offering price of up to $15.0 million, subject to the terms and conditions of the December 2021 ATM Agreement. The offering will terminate upon the earlier of (i) December 10, 2024 and (ii) termination of the December 2021 ATM Agreement as permitted therein.

On February 2, 2022, the Company entered into an amendment to the December 2021 ATM Agreement, pursuant to which, the aggregate offering amount of the shares of the Company's common stock which the Company may sell and issue through Ladenburg, as the sales agent, was increased from $15.0 million to $75.0 million (the "ATM Upsize").

As of December 31, 2021, the Company has issued 2,261,596 shares under the December 2021 ATM Agreement for a total net proceeds of $3.2 million.

During the nine months ended September 30, 2022, the Company issued an aggregate of 49,580,691 shares under the ATM Agreement for total net proceeds of $18.1 million after commissions and expenses of approximately $103,000.

Securities Purchase Agreement

On January 13, 2021, the Company entered into a securities purchase agreement, pursuant to which the Company agreed to issue and sell, in a registered public offering an aggregate of 1,479,290 shares of common stock at an offering price of $10.14 per share for gross proceeds of approximately $15.0 million before deducting $1.6 million placement agent fee and related offering expenses. The offering closed on January 15, 2021.

On April 29, 2021, the Company entered into another securities purchase agreement, pursuant to which the Company agreed to issue and sell, in a registered public offering through Ladenburg as the placement agent, an aggregate of 2,549,000 shares of common stock at an offering price of $4.23 per share for gross proceeds of approximately $10.8 million before deducting placement agent fees and related offering expenses of $948,000. The offering closed on May 3, 2022.

Subscription Agreement

On June 1, 2021, the Company entered into a subscription agreement with the SPAC and its sponsor, pursuant to which the SPAC agreed to issue and sell, in a private placement by the SPAC directly to the Company, units of the

SPAC, with each unit consisting of one ordinary share of the SPAC and a warrant to purchase a share, for gross proceeds of approximately €8.8 million (corresponding, as at June 1, 2021, to $10.8 million). The SPAC is an Italy special purpose acquisition company formed for the purpose of entering into a business combination with Napo EU, with the aim of developing the pharmaceutical activities of the SPAC/Napo EU combined entity in Europe. Each warrant will entitle the holder thereof to purchase one share at an exercise price of €10 per share at any time prior to the earlier of (i) the 10-year anniversary of the consummation of the business combination and (ii) the five-year anniversary of the listing of the combined entity on a public exchange.

On November 3, 2021, the SPAC issued 883,000 ordinary shares, each reserved to the exercise of warrants pursuant to the warrant agreement approved by the SPAC. As a result, the SPAC became a substantially owned subsidiary, at the same time, the related advances will be converted to investment at a stand-alone level, and will be eliminated at the consolidated level.

September 2021 PIPE Financing

On September 13, 2021, the Company entered into a securities purchase agreement (the "September 2021 PIPE Financing") with certain investors, pursuant to which the Company agreed to issue and sell to the investors in a private placement an aggregate of 309,242 unregistered shares of the Company's common stock for an aggregate purchase price of approximately $776,197 or $2.51 per share.

Noncontrolling Interest

As a result of the merger last November 3, 2021 between Napo EU and Dragon SPAC, the Company assumed a non-controlling interest amounting to $242,000 as of December 31, 2021 which represents noncontrolling interest held by an investor in Napo Therapeutics.

During the three and nine months ended September 30, 2022, noncontrolling interest decreased by $89,000 and $290,000, respectively due to the share in net loss on Napo Therapeutics' financial performance.

12. Stock-based Compensation

2013 Equity Incentive Plan

Effective November 1, 2013, the Company's BOD and sole stockholder adopted the Jaguar Health, Inc. 2013 Equity Incentive Plan (the "2013 Plan"). The 2013 Plan allows the Company's BOD to grant stock options, restricted stock awards and restricted stock unit awards to employees, officers, directors and consultants of the Company. Following the effective date of the IPO and after effectiveness of any grants under the 2013 Plan that were contingent on the IPO, no additional stock awards will be granted under the 2013 Plan. Outstanding grants continue to be exercisable; however, any unissued shares under the plan and any forfeitures of outstanding options do not rollover to the 2014 Stock Incentive Plan. There were 123 option shares outstanding at September 30, 2022 and December 31, 2021.

2014 Stock Incentive Plan

Effective May 12, 2015, the Company adopted the Jaguar Health, Inc. 2014 Stock Incentive Plan ("2014 Plan"). The 2014 Plan provides for the grant of options, restricted stock and restricted stock units to eligible employees, directors and consultants to purchase the Company's common stock. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes or our outstanding stock, the term must not exceed 5 years. The 2014 Plan that provides for automatic share increases on the first day of each fiscal year in the amount of 2% of the outstanding number of shares of the Company's common stock on the last day of the preceding calendar year. The 2014 Plan replaced the 2013 Plan except that all outstanding options under the 2013 Plan remain outstanding until exercised, canceled or expired.

As of September 30, 2022, there were 2,318,948 options outstanding and 172,550 options available for grant. As of December 31, 2021, there were 2,348,076 options outstanding and 619,480 options available for grant.

2020 New Employee Inducement Award Plan

Effective June 16, 2020, the Company adopted the Jaguar Health, Inc. New Employee Inducement Award Plan ("2020 Inducement Award Plan") and, subject to the adjustment provisions of the Inducement Award Plan, reserved 166,666 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Award Plan. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes or our outstanding stock, the term must not exceed 5 years. The 2020 Inducement Award Plan provides for the grant of non-statutory stock options, restricted stock units, restricted stock, and performance shares. The 2020 Inducement Award Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. The terms and conditions of the 2020 Inducement Award Plan are substantially similar to the Company's 2014 Stock Incentive Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, the only persons eligible to receive grants of equity awards under the Inducement Award Plan are individuals who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company.

On April 13, 2022, the Board of Directors of the Company approved an amendment to the 2020 Inducement Award Plan to reserve an additional 471,833 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Award Plan, thereby increasing the number of shares of the Company's common stock issuable thereunder from 500,000 shares to 971,833 shares.

As of September 30, 2022, there were 116,434 options outstanding and 522,065 options available for grant. As of December 31, 2021, there were 154,876 options outstanding and 11,790 options available for grant.

Stock Options and Restricted Stock Units ("RSUs")

The following table summarizes incentive plan activity for the three and nine months ended September 30, 2022 (unaudited):

(in thousands, except share and per share data)	Shares Available for Grant	Stock Options Outstanding	RSUs Outstanding	Weighted Average Stock Option Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value*
Outstanding at December 31, 2021	631,270	2,503,075	487,456	$ 9.44	8.35	$ 3
Additional shares authorized	2,889,495	—	—	—		—
Options granted	(3,333)	3,333	—	0.31		—
Options exercised	—	—	—	—		—
Options canceled	70,903	(70,903)	—	3.92		—
RSUs granted	(2,893,720)	—	2,893,720	—		—
Outstanding at September 30, 2022	694,615	2,435,505	3,381,176	$ 9.59	7.59	$ —
Exercisable at September 30, 2022		1,925,768		$ 10.76	7.36	$ —
Vested and expected to vest at September 30, 2022		2,379,802		$ 9.69	7.57	$ —

*Fair market value of JAGX common stock on September 30, 2022 was $0.16 per share.

The intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair market value of the Company's common stock for options that were in-the-money.

The number of options exercised during the nine months ended September 30, 2022, and 2021 were zero and 3,147, respectively.

The weighted average grant date fair value of stock options granted was $0.29 and $5.25 per share during the nine months ended September 30, 2022, and 2021, respectively.

The number of options that vested in the nine months ended September 30, 2022, and 2021 was 516,972 and 495,023, respectively. The grant date weighted average fair value of options that vested in the nine months ended September 30, 2022, and 2021 was $4.17 and $4.55, respectively.

Stock-Based Compensation

The following table summarizes stock-based compensation expense related to stock options, inducement stock options and RSUs for the three and nine months ended September 30, 2022, and 2021, and are included in the unaudited condensed consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Research and development expense	$ 354	$ 404	$ 1,067	$ 935
Sales and marketing expense	32	88	234	208
General and administrative expense	455	673	1,620	1,689
Total	$ 841	$ 1,165	$ 2,921	$ 2,832

As of September 30, 2022, the Company had $2.2 million of unrecognized stock-based compensation expense for options, inducement options and restricted stock units outstanding, which is expected to be recognized over a weighted-average period of 1.41 years.

The fair value of options granted during the three and nine months ended September 30, 2022, and 2021, respectively, were calculated using the range of assumptions set forth below:

	Nine Months Ended September 30,	
	2022	2021
	(unaudited)	
Volatility	164.0%	163.8 - 164.0 %
Expected term (years)	5.0	5.0
Risk-free interest rate	3.2%	0.5 - 1.0 %
Expected dividend yield	—	—

401(k) Plan

The Company sponsors a 401(k) defined contribution plan covering all employees. There were no employer contributions to the plan from plan inception through September 30, 2022.

13. Net Loss Per Share

The following table presents the calculation of basic and diluted net loss per share of common stock for the periods indicated:

(In thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Net loss attributable to common shareholders (basic and diluted)	$ (12,520)	$ (12,192)	$ (39,873)	$ (38,282)
Shares used to compute net loss per common share, basic and diluted	106,362,178	45,840,262	81,657,061	44,167,885
Net loss per share attributable to common shareholders, basic and diluted	$ (0.12)	$ (0.27)	$ (0.49)	$ (0.87)

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include stock options, convertible preferred stock, RSUs and common stock warrants have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the three and nine months ended September 30, 2022, and 2021 because their inclusion would be anti-dilutive.

	Nine Months Ended September 30,	
	2022	2021
	(unaudited)	
Options issued and outstanding	2,319,069	2,301,513
Inducement options issued and outstanding	116,449	156,204
Restricted stock units issued and outstanding	3,381,176	1,871
Warrants issued and outstanding	562,847	563,451
Total	6,379,541	3,023,039

As of November 14, 2022, there were 7,377,717 shares of common stock issued after the balance sheet date. Including these shares will have a material effect on the diluted net loss per common share in future periods.

14. Segment Information

The Company has two reportable segments-human health and animal health. The animal health segment is focused on developing and commercializing prescription and non-prescription products for companion and production animals. The human health segment is focused on developing and commercializing of human products and the ongoing commercialization of Mytesi, which is approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The accounting policies of the segments are the same as those described in the summary of significant accounting policies.

The Company's reportable segments net revenues and net loss for the three and nine months ended September 30, 2022, and 2021 consisted of the following:

(in thousands)	Three Months Ended September 30, 2022	2021	Nine Months Ended September 30, 2022	2021
	(unaudited)		(unaudited)	
Revenue from external customers				
Human Health	$ 3,133	$ 615	$ 8,513	$ 2,200
Animal Health	17	15	183	55
Consolidated Totals	$ 3,150	$ 630	$ 8,696	$ 2,255
Segment net income (loss)				
Human Health	$ (6,360)	$ (5,698)	$ (15,956)	$ (16,393)
Animal Health	(6,249)	(6,494)	(24,207)	(21,889)
Consolidated Totals	$ (12,609)	$ (12,192)	$ (40,163)	$ (38,282)

The Company's reportable segments assets consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
	(unaudited)	
Segment assets		
Human Health	$ 39,916	$ 42,250
Animal Health	128,693	115,580
Total	$ 168,609	$ 157,830

The reconciliation of segments assets to the consolidated assets is as follows:

(in thousands)	September 30, 2022	December 31, 2021
	(unaudited)	
Total assets for reportable segments	$ 168,609	$ 157,830
Less: Investment in subsidiary	(29,232)	(29,232)
Less: Intercompany loan	(88,090)	(75,333)
Consolidated Totals	$ 51,287	$ 53,265

15. Subsequent Events

Amended License Agreement

On October 11, 2022, the Company entered into an Amended and Restated License and Services Agreement (the "Amended License Agreement") with SynWorld. Pursuant to the Original License Agreement, (i) the Company (A) granted Synworld an exclusive license to commercialize a canine-specific pharmaceutical product utilizing crofelemer as its active drug substance, which product is marketed in the United States under the trademark Canalevia® and Canalevia-CA1 ("Product"), for the treatment, prevention or amelioration of diarrhea in dogs (the "Licensed Indication") in the People's Republic of China, excluding Hong Kong (the "Synworld Territory"), and (B) engaged Synworld as a service provider to prepare, submit and obtain regulatory approval of the Product for the Licensed Indication in the Synworld Territory on behalf of the Company (the "Services") and (ii) Synworld (A) agreed to pay the Company a license fee (the "License Fee") equal to $5 million, which fee is payable in monthly installments during the initial two-year term of the Original License Agreement, and (B) committed to purchasing up to $5 million worth of unregistered shares of common stock of the Company ("Common Stock") over the initial two-year term of the Original License Agreement (the "Subscription Shares"). As consideration for the Services to be provided by Synworld under the Original License Agreement, the Company would pay Synworld a service fee (the "Service Fee") of up to $5 million, payable in monthly installments in the form of unregistered shares of Common Stock over the initial two-year term of the Original License Agreement (the "Service Shares"). The price per Service Share would be equal to the Minimum Price (as defined under Nasdaq Listing Rule 5635(d)) of the Common Stock at the time of such issuance, provided that such price shall in no event be less than (A) $0.25 per share, with respect to such shares that are issued prior to the six-month anniversary of the effective date of the Amendment, and (B) $0.31 per share, with respect to such shares that are issued on or after the six-month anniversary of the effective date of the Amendment (collectively, the "Floor Price").

The Amended License Agreement, among other things, (i) removes (A) Synworld's commitment to purchase the Subscription Shares and (B) the Floor Price that the issuance of the Service Shares is subject to, such that the Service Shares will be issued at a price per share equal to the Minimum Price at the time of such issuance, and (ii) provides the Company with the discretion to elect to pay for the Synworld's Services either in cash or in the Service Shares in terms of each monthly installment.

In addition, the Amended License Agreement (i) provides the Company with a unilateral right to cause the parties to the Amended License Agreement to suspend their respective obligations under the Amended License Agreement without terminating such agreement, and (ii) acknowledges that (A) the License Fee due and payable by Licensee for September 2022, (B) the obligation of Licensee to purchase the Subscription Shares for September 2022, and (C) the Service Fee due and payable by the Company for September 2022 are all waived in full.

Consistent with the terms of the original license agreement, under no circumstances will the number of shares of common stock issued by the Company under the Amended License Agreement (i) exceed 19.99% of the total shares outstanding of the Company or (ii) result in the total number of shares of Common Stock held Synworld and its affiliates exceeding 19.99% of total shares outstanding of the Company at any given time, in each case unless stockholder approval is obtained.

December 2021 ATM Agreement

Subsequent to September 30, 2022, the Company has issued an additional 6,187,208 shares under the December 2021 ATM Agreement with a total net proceeds of $892,000.

Note Global Amendment #2

On October 17, 2022, the Borrower and Streeterville entered into an amendment (the "Note Global Amendment #2") with Streeterville to (i) the note purchase agreement, dated as of January 19, 2021, by and between Borrower and Streeterville (the "Note Purchase Agreement") and (ii) the secured promissory note in the original principal amount of $6,220,812.50 (the "Note") issued by Borrower to Streeterville as of January 19, 2021, pursuant to the Note Purchase Agreement, as amended by the global amendment, dated as of April 14, 2022, by and between Borrower and

Streeterville (the "Note Amendment"). Pursuant to the Note Global Amendment #2, (i) Streeterville will, under the Note Purchase Agreement, no longer be entitled to the Return Bonus (as defined in the Note Purchase Agreement) in the event of a sale by Borrower of the program to pursue the TDPRV (as defined in the Note Purchase Agreement); (ii) Borrower may not prepay the Note without Streeterville's prior written consent; and (iii) the deadline to begin the Phase 1 clinical trial for Lechlemer, as provided in the definition of the term "Trial Failure" in the Note, is extended from July 1, 2022 to July 1, 2023.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q, and with our audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K as of and for the year ended December 31, 2021 which was filed to SEC on March 11, 2022.

The discussion and analysis below includes certain forward-looking statements related to our research and development and commercialization of our products in the U.S., our future financial condition and results of operations and potential for profitability, the sufficiency of our cash resources, our ability to obtain additional equity or debt financing or other means of accelerating the payment of accounts receivable, if needed, possible partnering or other strategic opportunities for the development of our products, as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, which are all forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying our judgments concerning the future financial performance and other matters discussed in this document. The words "may," "will," "should," "plan," "believe," "estimate," "intend," "anticipate," "project," and "expect" and similar expressions are intended to connote forward-looking statements. All forward-looking statements involve certain risks, uncertainties and other factors described in our Annual Report on Form 10-K, that could cause our actual commercialization efforts, financial condition and results of operations, and business prospects and opportunities to differ materially from these expressed in, or implied by, those forward-looking statements. We caution investors not to place significant reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise forward-looking statements.

Overview

Jaguar Health, Inc. ("Jaguar" or the "Company") is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), focuses on developing and commercializing proprietary plant-based human pharmaceuticals for the global marketplace from plants or plant products used traditionally in rainforest areas. Napo's marketed drug Mytesi (crofelemer 125 mg delayed-release tablets) is a first-in-class oral botanical drug product approved by the U.S. Food and Drug Administration ("FDA") for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. To date, this is the only oral plant-based botanical prescription medicine approved under the FDA's Botanical Guidance. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Animal Health's Canalevia-CA1 (crofelemer delayed-release tablets) drug is the first and only oral plant-based prescription product that is FDA conditionally approved to treat chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1 is a canine-specific formulation of crofelemer. Napo Therapeutics S.p.A., Napo's majority owned Italian subsidiary, focuses on expanding crofelemer access in Europe.

Jaguar, formerly known as Jaguar Animal Health, Inc., was founded in San Francisco, California as a Delaware corporation on June 6, 2013 (inception). The Company was a majority-owned subsidiary of Napo until the close of the Company's initial public offering on May 18, 2015. The Company was formed to develop and commercialize first-in-class prescription and non-prescription products for companion and production animals and horses. The Company's first non-prescription commercial products, Neonorm Calf and Neonorm Foal, were launched in 2014 and 2016, respectively.

On July 31, 2017, Jaguar completed a merger with Napo pursuant to the Agreement and Plan of Merger dated March 31, 2017, by and among Jaguar, Napo, Napo Acquisition Corporation ("Merger Sub"), and Napo's representative (the "Merger Agreement"). In accordance with the terms of the Merger Agreement, upon the completion of the merger, Merger Sub merged with and into Napo, with Napo surviving as the wholly-owned subsidiary (the "Merger" or "Napo Merger"). Immediately following the Merger, Jaguar changed its name from "Jaguar Animal Health, Inc." to "Jaguar

Health, Inc." Napo now operates as a wholly-owned subsidiary of Jaguar focused on human health including the ongoing development of crofelemer and commercialization of Mytesi.

On March 15, 2021, Jaguar established Napo EU S.p.A (which changed its name in December 2021 to "Napo Therapeutics") based in Milan, Italy as a subsidiary of Napo. Napo Therapeutics' mission is to provide access to crofelemer in Europe to address significant rare/orphan disease indications, including, initially, two key orphan target indications: Short bowel syndrome (SBS) with intestinal failure, and congenital diarrheal disorders (CDD). On November 3, 2021, Napo Therapeutics merged with Dragon SPAC S.p.A. ("Dragon SPAC").

On December 21, 2021, we received conditional approval from the FDA for Canalevia-CA1 (crofelemer delayed-release tablets), our oral plant-based prescription drug and the only drug for the treatment of CID in dogs. Canalevia-CA1 is being commercialized as a prescription drug product under the Company's Jaguar Animal Health tradename, and as announced April 27, 2022, Canalevia-CA1 is now available from multiple leading veterinary distributors in the U.S. to veterinarians.

Canalevia-CA1 is a tablet that can be given orally twice a day and can be used for home treatment of CID. Canalevia-CA1 is a canine-specific formulation of crofelemer that is conditionally approved by the FDA under application number 141-552. Conditional approval allows for commercialization of the product while Jaguar Animal Health continues to collect the substantial evidence of effectiveness required for a full approval. We have received Minor Use in a Major Species (MUMS) designation from the FDA for Canalevia-CA1 to treat CID in dogs. FDA has established a "small number" threshold for minor use in each of the seven major species covered by the MUMS act. The small number threshold is currently 70,000 for dogs, representing the largest number of dogs that can be affected by a disease or condition over the course of a year and still have the use qualify as a minor use.

Most of the activities of the Company are focused on the commercialization of Mytesi and Canalevia-CA1 and the ongoing clinical development of crofelemer for the prophylaxis of diarrhea in adult patients receiving targeted cancer therapy. In the field of animal health, we are continuing limited activities related to developing and commercializing first in class gastrointestinal products for dogs, dairy calves and foals.

We believe Jaguar is poised to realize a number of synergistic, value adding benefits—an expanded pipeline of potential blockbuster human follow-on indications of crofelemer, and a second-generation anti secretory agent—upon which to build global partnerships. Jaguar, through Napo, holds global unencumbered rights for crofelemer, Mytesi, and Canalevia-CA1. Additionally, several of the drug product opportunities in Jaguar's crofelemer pipeline are backed by Phase 2 and proof of concept evidence from human clinical trials.

Crofelemer is a novel, first in class anti secretory agent which has a normalizing effect on electrolyte and fluid balance while acting locally in the gut, and this mechanism of action has the potential to benefit multiple disorders that cause gastrointestinal distress, including diarrhea and abdominal discomfort. Crofelemer is also in development for possible follow-on indications, including prophylaxis for cancer therapy related diarrhea ("CTD"); for rare disease indications for symptomatic treatment of infants and children with congenital diarrheal disorders ("CDD") and for adult and pediatric patients with short bowel syndrome ("SBS") with intestinal failure. Crofelemer has received orphan drug designation (ODD) for short bowel syndrome (SBS) in the US and in EU. Furthermore, the drug is being evaluated for management of diarrhea and abdominal discomfort in inflammatory bowel disease ("IBD"); diarrhea-predominant irritable bowel syndrome ("IBS-D"); and for idiopathic/functional diarrhea. A second-generation proprietary anti secretory agent, NP-300 (lechlemer), is undergoing preclinical development for symptomatic relief and treatment of diarrhea in patients with acute infection from cholera.

Financial Operations Overview

On a consolidated basis, we have not yet generated enough revenue to date to achieve break even or positive cash flows, and we expect to continue to incur significant research and development and other expenses. Our net loss was $40.2 million and $38.3 million for the nine months ended September 30, 2022, and 2021, respectively. As of September 30, 2022, we had a total stockholders' equity of $3.6 million, an accumulated deficit of $259.4 million, and cash of $10.6 million. We expect to continue to incur losses and experience increased expenditures for the foreseeable

future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin additional commercialization activities.

Revenues

Our product and collaboration revenue consist of the following:

- Revenues from the sale of our human drug Mytesi, which is sold through distributors and wholesalers and specialty pharmacies.

- Revenues from the sale of our animal products branded as Canalevia-CA1, Neonorm Calf and Neonorm Foal. Our Canalevia-CA1, Neonorm and botanical extract products are primarily sold to distributors, who then sell the products to the end customers.

- Our 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 product that will expire within six 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.

See “Results of Operations” below for more detailed discussion on revenues.

Cost of Revenue

Cost of revenue consists of direct drug substance and drug product materials expense, direct labor, distribution fees, royalties and other related expenses associated with the sale of our products.

Research and Development Expense

Research and development expenses consist primarily of clinical and contract manufacturing expense, personnel and related benefits expense, stock-based compensation expense, employee travel expense, and reforestation expenses. Clinical and contract manufacturing expense consists primarily of costs to conduct stability, safety and efficacy studies, and manufacturing startup at an outsourced API provider in Italy. It also includes expenses with a third-party provider for the transfer of the Mytesi manufacturing process, and the related feasibility and validation activities.

We typically use our employee and infrastructure resources across multiple development programs. We track outsourced development costs by prescription drug product candidate and non-prescription product and we track personnel or other internal costs related to development to specific programs or development compounds.

The timing and amount of our research and development expenses will depend largely upon the outcomes of current and future trials for our prescription drug product candidates as well as the related regulatory requirements, the outcomes of current and future species-specific formulation studies for our non-prescription products, manufacturing costs and any costs associated with the advancement of our line extension programs. We cannot determine with certainty the duration and completion costs of the current or future development activities.

The duration, costs and timing of trials, formulation studies and development of our prescription drug and non-prescription products will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional clinical trials, formulation studies and other research and development activities;

- future clinical trial and formulation study results;

- potential changes in government regulations; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a prescription drug product candidate or non-prescription product could mean a significant change in the costs and timing associated with our development activities.

We expect research and development expense to increase due to the start-up costs associated with our clinical trials for other indications.

Sales and Marketing Expense

Sales and marketing expenses consist of personnel and related benefits expense, stock-based compensation expense, direct sales and marketing expense, employee travel expense, and management consulting expense. We currently incur sales and marketing expenses to promote Mytesi. We do not have significant marketing or promotional expenses related to Neonorm Calf or Neonorm Foal in the three and nine months ended September 30, 2022, and 2021.

We expect sales and marketing expense to increase going forward as we focus on expanding our market access activities and commercial partnerships for the development of follow-on indications of Mytesi and crofelemer.

General and Administrative Expense

General and administrative expenses consist of personnel and related benefits expense, stock-based compensation expense, employee travel expense, legal and accounting fees, rent and facilities expense, and management consulting expense.

In the near term, we expect general and administrative expense to remain flat as we focus on our pipeline development and market access expansion. This will include efforts to grow the business.

Interest Expense

Interest expense consists primarily of non-cash and cash interest costs related to our borrowings.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"), requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the consolidated financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. Our significant account policies are described in Note 2 of the condensed consolidated financial statements. Our critical accounting policies and estimates were described in Part II, Item 7, Critical Accounting Policies and Estimates, in our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Comparison of the nine months ended September 30, 2022, and 2021

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the nine months ended September 30, 2022, and 2021 together with the change in such items in dollars and as a percentage.

	Nine Months Ended September 30,			
(in thousands)	2022	2021	Variance	Variance %
Product revenue	$ 8,696	$ 2,255	$ 6,441	285.6 %
Total revenue	8,696	2,255	6,441	285.6 %
Operating Expenses				
Cost of product revenue	1,524	1,864	(340)	(18.2)%
Research and development	13,336	9,597	3,739	39.0 %
Sales and marketing	7,089	6,596	493	7.5 %
General and administrative	14,876	12,450	2,426	19.5 %
Series 3 warrants inducement expense	—	1,462	(1,462)	(100.0)%
ELOC warrants inducement expense	—	172	(172)	(100.0)%
Total operating expenses	36,825	32,141	4,684	14.6 %
Loss from operations	(28,129)	(29,886)	1,757	(5.9)%
Interest expense	(10,089)	(5,988)	(4,101)	68.5 %
Loss on extinguishment of debt	(2,187)	(753)	(1,434)	190.4 %
Change in fair value of financial instruments and hybrid instrument designated at Fair Value Option	652	(1,639)	2,291	(139.8)%
Other expense, net	(410)	(16)	(394)	2,462.5 %
Loss before income tax	(40,163)	(38,282)	(1,881)	4.9 %
Income tax expense	—	—	—	100.0 %
Net loss and comprehensive loss	(40,163)	(38,282)	(1,881)	4.9 %
Net loss attributable to noncontrolling interest	(290)	—	(290)	100 %
Net loss attributable to common shareholders	$ (39,873)	$ (38,282)	$ (1,591)	4 %

Revenue

Product revenue

We transitioned from selling to the wholesalers that resell the product to retail pharmacies to the closed Specialty Pharmacy distribution networks throughout the year 2021 and we fully transitioned in the fourth quarter of the same year.

Sales of Mytesi are recognized as revenue when the products are delivered to the wholesalers and to specialty pharmacies. Our gross revenues from the sale of Mytesi were $10.9 million and $12.7 million in the nine months ended September 30, 2022, and 2021, respectively. The decrease of about $1.7 million is largely due to the transition from Title model to the Specialty Pharmacy distribution networks.

Though the transition to a closed network of specialty pharmacies has resulted in fewer bottles sold, it generated significant reductions in distribution costs, a higher average net price, and assisted our market access strategy intended to help remove access barriers for patients prescribed Mytesi and includes services such as higher level of support for prior authorizations, appeals, adherence counseling, and home delivery options.

Medicaid and AIDS Drug Assistance Program ("ADAP") rebates accounted for $1.5 million and $2.9 million for the nine months ended September 30, 2022, and 2021, respectively, a decrease of $1.4 million. Sales discounts and sales returns were $954,000 and $6.0 million for the nine months ended September 30, 2022, and 2021, respectively, a

decrease of $5.0 million. The wholesaler fees were eliminated in the nine months ended September 30, 2022 as compared to $1.5 million in the nine months ended September 30, 2021.

Due to the Company's arrangements, including elements of variable consideration, gross product sales are reduced in order to reflect the expected consideration to arrive at net product sales. Deductions to reduce gross product sales to net product sales in the nine months ended September 30, 2022, and 2021 were as follows:

	Nine Months Ended September 30,			
(in thousands)	2022	2021	Variance	Variance %
Gross product sales				
Mytesi	$ 10,929	$ 12,665	$ (1,736)	(13.7)%
Canalevia	143	—	143	100.0 %
Neonorm	40	54	(14)	(25.9)%
Total gross product sales	11,112	12,719	(1,607)	(12.6)%
Medicaid rebates	(1,550)	(2,900)	1,350	(46.6)%
Sales discounts	(954)	(5,932)	4,978	(83.9)%
Sales returns	88	(104)	192	(184.6)%
Wholesaler fee	—	(1,528)	1,528	(100.0)%
Net product sales	$ 8,696	$ 2,255	$ 6,441	285.6 %

Our gross product revenues were $8.7 million and $12.7 million for the nine months ended September 30, 2022, and 2021, respectively. These periods reflect revenue from the sale of our human drug Mytesi and our animal products branded as Neonorm Calf and Neonorm Foal.

Our Canalevia product was recently launched in 2022 with revenues of $143,000 and zero for the nine months ended September 30, 2022, and 2021, respectively. Sales and marketing expenses for Canalevia products are not significant during 2022.

Our Neonorm product revenues were $40,000 and $54,000 for the nine months ended September 30, 2022, and 2021, respectively. Sales and marketing expenses for Neonorm products are not significant during 2022 and during the same period in 2021.

Cost of Product Revenue

	Nine Months Ended September 30,			
(in thousands)	2022	2021	Variance	Variance %
Cost of Product Revenue				
Material cost	$ 768	$ 797	$ (29)	(3.6)%
Direct labor	526	788	(262)	(33.2)%
Royalties	33	—	33	100.0 %
Distribution fees	12	168	(156)	(92.9)%
Other	185	111	74	66.7 %
Total	$ 1,524	$ 1,864	$ (340)	(18.2)%

Cost of product revenue decreased $340,000 from $1.9 million in the nine months ended September 30, 2021 to $1.5 million for the same period in 2022. The decrease in the cost of product revenue period over period was largely attributable to lower sales volume resulting in less cost of materials for bottles sold in the nine months ended September 30, 2021.

Research and Development

The following table presents the components of research and development ("R&D") expense for the nine months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Nine Months Ended September 30, 2022	2021	Variance	Variance %
Research and Development:				
Personnel and related benefits	$ 4,256	$ 2,827	$ 1,429	50.5 %
Clinical and contract manufacturing	5,866	3,303	2,563	77.6 %
Stock-based compensation	1,067	935	132	14.1 %
Materials expense and tree planting	219	284	(65)	(22.9)%
Travel, other expenses	93	10	83	830.0 %
Other	1,835	2,238	(403)	(18.0)%
Total	$ 13,336	$ 9,597	$ 3,739	39.0 %

The increase in R&D expense of $3.7 million in the nine months ended September 30, 2022 compared to the same period in 2021 was largely due to:

- Personnel and related benefits increased $1.4 million from $2.8 million in the nine months ended September 30, 2021 to $4.3 million in the same period in 2022 due to the additional headcount.

- Clinical and contract manufacturing expenses increased $2.6 million from $3.3 million in the nine months ended September 30, 2021 to $5.9 million in the same period in 2022 largely due to increased clinical trial activities related to start-up of CTD and other indications, additional CMC manufacturing, consulting and contractors' expenses, and cholera/lechlemer research expenses.

- Stock-based compensation increased $132,000 from $935,000 in the nine months ended September 30, 2021 to $1.1 million in the same period in 2022 primarily due to new options and RSUs granted during the period.

- Materials expense and tree planting decreased $65,000 from $284,000 in the nine months ended September 30, 2021 to $219,000 in the same period in 2022 primary due to lower number of activities involving tree planting activities.

- Travel, and other expenses increased $83,000 from $10,000 in the nine months ended September 30, 2021 to $93,000 in the same period in 2022 primarily due to more travel activities with the clinical trials.

- Other expenses consisting of consulting, formulation and regulatory fees decreased $403,000 from $2.2 million in the nine months ended September 30, 2021 to $1.8 million in the same period in 2022.

Sales and Marketing

The following table presents the components of sales and marketing ("S&M") expense for the nine months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Nine Months Ended September 30, 2022	2021	Variance	Variance %
Sales and Marketing:				
Direct marketing fees and expense	$ 2,874	$ 2,544	$ 330	13.0 %
Personnel and related benefits	2,699	2,887	(188)	(6.5)%
Stock-based compensation	234	208	26	12.5 %
Other	1,282	957	325	34.0 %
Total	$ 7,089	$ 6,596	$ 493	7.5 %

The increase in S&M expense of $493,000 in the nine months ended September 30, 2022 compared to the same period in 2022 was largely due to:

- Direct marketing fees and expenses increased $330,000 from $2.5 million in the nine months ended September 30, 2021 to $2.9 million in the same period in 2022 due to increased patient access programs and other Mytesi marketing initiatives.
- Personnel and related benefits decreased $188,000 from $2.9 million in the nine months ended September 30, 2021 to $2.7 million in the same period in 2022 due to decrease in headcount in sales and marketing.
- Stock-based compensation increased $26,000 from $208,000 in the nine months ended September 30, 2021 to $234,000 in the same period in 2022 primarily due to new options and RSUs granted during the period.
- Other expenses increased $325,000 from $957,000 in the nine months ended September 30, 2021 to $1.3 million in the same period in 2022 due to higher consulting and contractor services and a greater number of travels for sales and marketing personnel.

General and Administrative

The following table presents the components of general and administrative ("G&A") expense for the nine months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Nine Months Ended September 30, 2022	2021	Variance	Variance %
General and Administrative:				
Personnel and related benefits	$ 3,574	$ 2,469	$ 1,105	44.8 %
Public company expense	3,338	2,045	1,293	63.2 %
Stock-based compensation	1,620	1,689	(69)	(4.1)%
Legal services	1,678	1,532	146	9.5 %
Audit, tax and accounting services	921	828	93	11.2 %
Rent and lease expense	341	191	150	78.5 %
Travel, other expenses	227	84	143	170.2 %
Other	3,177	3,612	(435)	(12.0)%
Total	$ 14,876	$ 12,450	$ 2,426	19.5 %

The increase in G&A expenses of $2.4 million in the nine months ended September 30, 2022 compared to the same period in 2022 was largely due to:

- Personnel and related benefits increased $1.1 million from $2.5 million in the nine months ended September 30, 2021 to $4.4 million in the same period in 2022, due to additional headcount and accrued bonus.
- Public company expense increased $1.3 million from $2.0 million in the nine months ended September 30, 2021 to $3.3 million in the same period in 2022, largely attributable to the investor relations and communications consulting expenses, and expenses for the annual shareholder meeting.
- Audit, tax and accounting services fees increased $93,000 from $828,000 in the nine months ended September 30, 2021 to $921,000 in the same period in 2022 mostly due to change in accounting firm and higher number of complex transactions.
- Rent and lease expense increased $150,000 from $191,000 in the nine months ended September 30, 2021 to $341,000 in the same period in 2022 primarily due to increase in fees related to occupancy of new spaces and use of vehicles.
- Travel, and other expenses increased $143,000 from $84,000 in the nine months ended September 30, 2021 to $227,000 in the same period in 2022 primarily due to higher travel activities related to administrative function.
- Other expenses decreased $435,000 from $3.6 million in the nine months ended September 30, 2021 to $3.2 million in the same period in 2022 due to lower consulting and contractual fees, compliance expense and dues and subscription fees.

Series 3 Warrants Inducement Expense

In January 2021, the Company issued 135,416 Series 3 Warrants to a certain investor for the exercise of 135,416 Bridge Note Warrants in accordance with the May 2020 Modification of the 2019 Bridge Note Warrants and Inducement Offer. These Series 3 Warrants were valued at $1.5 million using the Black-Scholes-Merton option pricing model on the issuance date.

Interest Expense

Interest expense increased $4.1 million from $6.0 million in the nine months ended September 30, 2021 to $10.1 million for the same period in 2022 primarily due to interest expense incurred on royalty interest agreements and Exchange Note 2.

Loss on Extinguishment of Debt

The increase in the loss on extinguishment of debt from $753,000 in the nine months ended September 30, 2022 to $2.2 million in the same period in 2022 is due to the extinguishment loss from the exchange of the outstanding balance of Iliad's royalty agreements for shares of the Company's common stock.

Change in Fair Value of Financial Instruments and Hybrid Instrument Designated at FVO

Change in fair value of financial instrument and hybrid instrument designated at FVO increased $2.3million from a loss of $1.6 million in the nine months ended September 30, 2021 to a gain of $652,000 for the same period in 2022 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.

Comparison of the Three months ended September 30, 2022, and 2021

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the three months ended September 30, 2022, and 2021 together with the change in such items in dollars and as a percentage.

	Three Months Ended September 30,			
(in thousands)	2022	2021	Variance	Variance %
Product revenue	$ 3,150	$ 630	$ 2,520	400.0 %
Total revenue	3,150	630	2,520	400.0 %
Operating expenses				
Cost of product revenue	613	617	(4)	(0.6)%
Research and development	5,940	3,312	2,628	79.3 %
Sales and marketing	2,109	2,261	(152)	(6.7)%
General and administrative	4,384	3,969	415	10.5 %
ELOC warrants inducement expense	—	—	—	100.0 %
Total operating expenses	13,046	10,159	2,887	28.4 %
Loss from operations	(9,896)	(9,529)	(367)	3.9 %
Interest expense	(2,731)	(2,078)	(653)	31.4 %
Other expense, net	(158)	(20)	(138)	690.0 %
Change in fair value of financial instruments and hybrid instrument designated at Fair Value Option	176	(565)	741	(131.2)%
Loss before income tax	(12,609)	(12,192)	(417)	3.4 %
Income tax expense	—	—	—	100.0 %
Net loss and comprehensive loss	(12,609)	(12,192)	(417)	3.4 %
Net loss attributable to noncontrolling interest	(89)	—	(89)	100 %
Net loss attributable to common shareholders	$ (12,520)	$ (12,192)	$ (417)	3.4 %

Revenue

Gross product sales equal the number of bottles sold multiplied by WAC. Due to the Company's arrangements, including elements of variable consideration, gross product sales are reduced in order to reflect the expected consideration to arrive at net product sales. Deductions to reduce gross product sales to net product sales in the three months ended September 30, 2022, and 2021 were as follows:

	Three Months Ended September 30,			
(in thousands)	2022	2021	Variance	Variance %
Gross product sales				
Mytesi	$ 3,863	$ 3,184	$ 679	21.3 %
Canalevia	12	—	12	100.0 %
Neonorm	5	15	(10)	(66.7)%
Total gross product sales	3,880	3,199	681	21.3 %
Medicaid rebates	(523)	(449)	(74)	16.5 %
Sales discounts	(316)	(1,599)	1,283	(80.2)%
Sales returns	109	(36)	145	(402.8)%
Wholesaler fees	—	(485)	485	(100.0)%
Net product sales	$ 3,150	$ 630	$ 2,520	400.0 %

Our gross product revenues were $3.9 million and $3.2 million for the three months ended September 30, 2022, and 2021, respectively. These periods reflect revenue from the sale of our human drug Mytesi and our animal products branded as Canalevia-CA1, Neonorm Calf and Neonorm Foal.

Our Canalevia product was recently launched in 2022 with revenues of $12,000 and zero for the three months ended September 30, 2022, and 2021, respectively. Sales and marketing expenses for Canalevia products are not significant during 2022.

Our Neonorm product revenues were $5,000 and $15,000 for the three months ended September 30, 2022, and 2021, respectively. Sales and marketing expenses for Neonorm products are not significant during 2022 and during the same period in 2021.

Cost of Product Revenue

(in thousands)	Three Months Ended September 30, 2022	2021	Variance	Variance %
Cost of Product Revenue				
Material cost	$ 245	$ 208	$ 37	17.8 %
Direct labor	200	275	(75)	(27.3)%
Royalties	13	—	13	100.0 %
Distribution fees	5	92	(87)	(94.6)%
Other	150	42	108	257.1 %
Total	$ 613	$ 617	$ (4)	(0.6)%

Cost of product revenue decreased $4,000 from $617,000 in the three months ended September 30, 2021 to $613,000 for the same period in 2022.

Research and Development

The following table presents the components of R&D expense for the three months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Three Months Ended September 30, 2022	2021	Variance	Variance %
Research and Development:				
Personnel and related benefits	$ 1,345	958	$ 387	40.4 %
Clinical and contract manufacturing	3,369	1,257	2,112	168.0 %
Stock-based compensation	354	404	(50)	(12.4)%
Materials expense and tree planting	78	116	(38)	(32.8)%
Travel, other expenses	19	6	13	216.7 %
Other	775	571	204	35.7 %
Total	$ 5,940	$ 3,312	$ 2,628	79.3 %

The increase in R&D expense of $2.6 million for the three months ended September 30, 2022 compared the same period in 2021 was due primarily to:

- Personnel and related benefits increased $387,000 from $1.0 million in the three months ended September 30, 2021 to $1.3 million in the same period in 2022 due to an increase in bonus and salaries and benefits largely from the additional headcount.

- Clinical and contract manufacturing expense increased $2.1 million from $1.3 million in the three months ended September 30, 2021 to $3.4 million in the same period in 2022 primarily due to increased clinical trial activities related to CTD and SBS.

- Other expenses consisting primarily of consulting, formulation and regulatory fees increased $204,000 from $571,000 in the three months ended September 30, 2021 to $775,000 in the same period in 2022.

Consulting expenses increased due to an increase in clinical trial consultants. Direct R&D testing costs also increased due to an increased in R&D work.

Sales and Marketing

The following table presents the components of S&M expense for the three months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Three Months Ended September 30, 2022	2021	Variance	Variance %
Sales and Marketing:				
Direct marketing fees and expense	$ 749	$ 698	$ 51	7.3 %
Personnel and related benefits	854	1,006	(152)	(15.1)%
Stock-based compensation	32	88	(56)	(63.6)%
Other	474	469	5	1.1 %
Total	$ 2,109	$ 2,261	$ (152)	(6.7)%

The decrease in S&M expense of $152,000 in the three months ended September 30, 2022 compared to the same period in 2021 was due primarily to:

- Personnel and related benefits decreased $152,000 from $1.0 million in the three months ended September 30, 2021 to $854,000 in the same period in 2022 due to decrease in personnel within Commercial Operations.

- Stock-based compensation decreased $56,000 from $88,000 in the three months ended September 30, 2021 to $32,000 in the same period in 2022 due to decrease in the volume of option grants restricted stock units granted in the second quarter of 2022 related to sales and marketing personnel.

General and Administrative

The following table presents the components of G&A expense for the three months ended September 30, 2022, and 2021 together with the change in such components in dollars and as a percentage:

(in thousands)	Three Months Ended September 30, 2022	2021	Variance	Variance %
General and Administrative:				
Personnel and related benefits	$ 678	$ 706	$ (28)	(4.0)%
Public company expense	1,731	564	1,167	206.9 %
Legal services	517	461	56	12.1 %
Stock-based compensation	455	673	(218)	(32.4)%
Rent and lease expense	45	92	(47)	(51.1)%
Audit, tax and accounting services	520	129	391	303.1 %
Travel, other expenses	29	69	(40)	(58.0)%
Other	409	1,275	(866)	(67.9)%
Total	$ 4,384	$ 3,969	$ 415	10.5 %

The increase in G&A expenses of $415,000 in the three months ended September 30, 2022 compared to the same period in 2021 was due primarily to:

- Public company expense increased $1.2 million from $564,000 for the three months ended September 30, 2021 to $1.7 million in the same period in 2022 largely attributable to the increase in investor relations and communications consulting expenses, and expenses for the annual shareholder meeting.

- Stock-based compensation expense decreased $218,000 from $673,000 in the three months ended September 30, 2021 to $455,000 in the same period in 2022 due to the decrease in the volume of option grants restricted stock units granted in the second quarter of 2022 related to finance and administrative personnel.

- Rent and lease expense decreased $47,000 from $92,000 in the three months ended September 30, 2021 to $45,000 in the same period in 2022 as a result of less occupancy of new spaces and use of vehicles during the three-month period.

- Audit, tax and accounting services fees increased $391,000 from $129,000 in the three months ended September 30, 2021 to $520,000 in the same period in 2022 mostly due to the increased audit fees related to complex debt and equity transactions.

- Travel and other expenses decreased $40,000 from $69,000 in the three months ended September 30, 2021 to $29,000 in the same period in 2022 mostly due to the decrease in transportation and travels.

- Other expenses which include dues and subscriptions and insurance fees decreased $866,000 from $1.3 million in the three months ended September 30, 2021 to $409,000 in the same period in 2022 due to lower D&O premium.

Series 3 Warrants Inducement Expense

In January 2021, the Company issued 135,416 Series 3 Warrants to a certain investor for the exercise of 135,416 Bridge Note Warrants in accordance with the May 2020 Modification of the 2019 Bridge Note Warrants and Inducement Offer. These Series 3 Warrants were valued at $1.5 million using the Black-Scholes-Merton option pricing model on the issuance date.

Interest Expense

Interest expense increased $653,000 from $2.1 million in the three months ended September 30, 2021 to $2.7 million for the same period in 2022 primarily due to interest expense incurred on royalty interest agreements and Exchange Note 2.

Change in Fair Value of Financial Instruments and Hybrid Instrument Designated at FVO

Change in fair value of financial instrument and hybrid instrument designated at FVO increased $741,000 from a loss of $565,000 in the three months ended September 30, 2021 to a gain of $176,000 for the same period in 2022 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses since our inception. For the nine months ended September 30, 2022, and 2021, we had net losses of $40.2 million and $38.3 million, respectively. We expect to incur additional losses in the near-term future. At September 30, 2022, we had an accumulated deficit of $259.4 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

We had cash of $10.6 million as of September 30, 2022. We do not believe our current capital is sufficient to fund our operating plan through one year from the issuance of these unaudited condensed consolidated financial statements.

We have funded our operations primarily through the issuance of debt and equity securities, in addition to sales of our commercial products. Cash provided by financing activities in the nine months ended September 30, 2022 were generated from the issuance of an aggregate of 49,850,691 shares of common stock under the ATM Agreement for total net proceeds of $17.8 million.

The Company also raised an additional net proceeds of $892,000 from the issuance of 6,187,208 shares of common stock under the ATM agreement between October 1, 2022 and November 14, 2022.

We expect our expenditures will continue to increase as we continue our efforts to develop our products and continue development of our pipeline in the near term. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan. We still plan to finance our operations and capital funding needs through equity and/or debt financing as well as revenue from future product sales. However, there can be no assurance that additional funding will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. If we are unable to obtain an adequate level of financing needed for the long-term development and commercialization of our products, we will need to curtail planned activities and reduce costs. Doing so will likely have an adverse effect on our ability to execute on our business plan.

Cash Flows for the Nine Months Ended September 30, 2022 Compared to Nine Months Ended September, 2021

The following table shows a summary of cash flows for the nine months ended September 30, 2022, and 2021:

(in thousands)	Nine Months Ended September 30, 2022	2021
Total cash used in operating activities	$ (26,681)	$ (26,047)
Total cash used in investing activities	(1,314)	(10,484)
Total cash provided by financing activities	21,543	40,816
Effects of foreign exchange rate changes on assets and liabilities	(38)	—
Net (decrease) increase in cash	$ (6,490)	$ 4,285

Cash Used in Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities of $26.7 million resulted from our net loss of $40.2 million adjusted by the amortization of debt discounts and debt issuance costs of $8.8 million, loss on extinguishment of debt of $2.2 million, stock-based compensation of $2.8 million, depreciation and amortization expenses of $1.5 million, change in fair value of financial instrument and hybrid instrument designated at FVO of $652,000, amortization of operating lease right-of-use asset of $208,000, shares issued upon exercise of RSUs and stock options of 100,000, shares issued in exchange of services of $354,000, and changes in operating assets and liabilities of $2.1 million.

During the nine months ended September 30, 2021, net cash used in operating activities of $26.0 million resulted from our net loss of $38.3 million adjusted by the amortization of debt discounts and debt issuance costs of $3.6 million, stock-based compensation of $2.8 million, change in fair value of financial instrument and hybrid instrument designated at FVO of $1.6 million, Series 3 Warrants inducement expense of $1.5 million, depreciation and amortization expenses of $1.3 million, loss on extinguishment of debt of $753,000, ELOC Warrants inducement expense of $172,000, derecognition of debt discount on the settlement of receivables secured borrowing of $49,000, amortization of operating lease right-of-use asset of $45,000, shares issued as payment for services amounting to $16,000, and changes in operating assets and liabilities of $344,000.

Cash Used in Investing Activity

During the nine months ended September 30, 2022, cash used in investing activities of $1.3 million consisted of cash used to purchase intangible assets and property and equipment.

During the nine months ended September 30, 2021, cash used in investing activity was $10.5 million which consisted of $10.5 million advances for future capital investment and $6,000 cash used to purchase property and equipment.

Cash Provided by Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities of $21.8 million consisted of $17.8 million in net proceeds from shares issued in an At the Market offering $4.0 million and notes payable from Streeterville, offset by $118,000 repayment of insurance financing, and $100,000 in principal payments of the notes payable.

During the nine months ended September 30, 2021, net cash provided by financing activities of $40.8 million consisted of $23.2 million in net proceeds received from shares issued in registered public offering, $11.0 million in net proceeds received from issuance of notes payable, $5.4 million in net proceeds from shares issued in an At the Market offering, $2.0 million in net proceeds received from shares issued on conversion of Series 1, Series 2, and 2019 Bridge Note Warrants, $1.8 million in net proceeds received from shares issued in PIPE financing, $4,000 in net proceeds from exercise of stock options, offset by $1.8 million repayment of receivables secured borrowing, $588,000 repayment of

insurance financing, $100,000 in principal payments of the notes payable and $35,000 payment of ELOC warrants offering costs.

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, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or15d-15(e) under the Exchange Act, of 1934, as mended (the "Exchange Act")) as of the end of the period covered by this report. Based on such evaluation, our Chief Executive Office and Principal Financial and Accounting Officer have concluded that, as of the end of such period, our disclosure controls and procedures were effective.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 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 to 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, 2022 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, 2022, our internal control over financial reporting was effective 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 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 an SRC and are not subject to auditor attestation requirements under applicable SEC rules.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. — 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 risk 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, as well as other factors affecting the Company's financial condition and operating results, past financial performance should not be considered to be 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 a sufficient amount of products to cover such.

Since March 2020, we have sold ***payments, which may strain our cash resources*** 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 2021, even if we do not sell a sufficient amount of product to cover such payments, which may strain our cash resources. The total minimum royalty payments will be $0.4 million in 2022, $18.0 million in 2023, $14.6 million in 2024, $18.9 million in 2025, and $5.3 million in 2026.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 1, 2022, the Company entered into an agreement, dated September 1, 2022, with Corporate Profile LLC, pursuant to which the Company agreed to issue 42,000 shares of the Company's common stock to Corporate Profile LLC as partial consideration for investor relations services, which shares are issuable in three tranches: 12,000 shares were issued on September 26, 2022, 15,000 shares will be issued on December 1, 2022 and 15,000 shares will be issued on April 1, 2023.

The offers, sales, and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Regulation D or Regulation S promulgated

thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

Other than equity securities issued in transactions disclosed above and on our Current Report on Form 8-K filed with the SEC on August 18, 2022, August 23, 2022 and August 30, 2022, 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.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description
3.1	Certificate of Designation of Series E Preferred Stock. (incorporated by reference to Exhibit 3.1 to the Form 8-K of Jaguar Health, Inc. filed August 23, 2022, File No. 001-36714).
3.2	Certificate of Sixth 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 of Jaguar Health, Inc. filed September 30, 2022, File No. 001-36714).
4.2	Royalty Interest, dated August 24, 2022, by and between Jaguar Health, Inc. and Streeterville Capital, LLC. (incorporated by reference to Exhibit 4.1 to the Form 8-K of Jaguar Health, Inc. filed August 30, 2022, File No. 001-36714).
10.1#	Amended and Restated License Agreement, dated July 19, 2022, by and between Napo Pharmaceuticals, Inc. and Napo Therapeutics S.p.A. (incorporated by reference to Exhibit 10.1 to the Form 8-K of Jaguar Health, Inc. filed July 20, 2022, File No. 001-36714).
10.2	Securities Purchase Agreement, dated August 18, 2022, by and between Jaguar Health, Inc. and SynWorld Technologies Corporation (incorporated by reference to Exhibit 10.1 to the Form 8-K of Jaguar Health, Inc. filed August 23, 2022, File No. 001-36714).
10.3	First Amendment to the License and Services Agreement, dated August 18, 2022, by and between Jaguar Health, Inc. and SynWorld Technologies Corporation (incorporated by reference to Exhibit 10.2 to the Form 8-K of Jaguar Health, Inc. filed August 23, 2022, File No. 001-36714).
10.4#	Manufacturing Services Agreement, dated June 10, 2022, by and between Napo Pharmaceuticals, Inc. and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K/A of Jaguar Health, Inc. filed August 24, 2022, File No. 001-36714).
10.5	Royalty Interest Purchase Agreement, dated August 24, 2022, by and between Jaguar Health, Inc. and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K of Jaguar Health, Inc. filed August 30, 2022, File No. 001-36714).
10.6	Amended and Restated License and Services Agreement, dated October 11, 2022, by and among Jaguar Health, Inc., SynWorld Technologies Corporation, C&E Telecom, LTD and Tao Wang (incorporated by reference to Exhibit 10.1 to the Form 8-K of Jaguar Health, Inc. filed October 14, 2022, File No. 001-36714).

10.7	Global Amendment, dated October 17, 2022, by and among Jaguar Health, Inc., Napo Pharmaceuticals, Inc. and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K of Jaguar Health, Inc. filed October 21, 2022, File No. 001-36714).
31.1*	Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
31.2*	Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* 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 "filed" 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.

Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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.

Date: November 14, 2022

JAGUAR HEALTH, INC.

By: /s/ Carol R. Lizak
Principal Financial and Accounting Officer

Exhibit 31.1

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION 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, 2022;

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.

Date: November 14, 2022

/s/ Lisa A. Conte
Lisa A. Conte
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION 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, 2022;

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.

Date: November 14, 2022

/s/ Carol Lizak
Carol Lizak
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

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

Date: November 14, 2022

/s/ Lisa A. Conte
Lisa A. Conte
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

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

Date: November 14, 2022

/s/ Carol Lizak
Carol Lizak
Principal Financial and Accounting Officer