

GUIDED THERAPEUTICS INC  
Form 10-Q  
November 14, 2018

**UNITED STATES SECURITIES AND  
EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT 1934

For the quarterly period ended September 30, 2018

*Commission File No. 0-22179*

**GUIDED THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

58-2029543

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

5835 Peachtree Corners East, Suite D

Norcross, Georgia 30092

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(Address of principal executive offices) (Zip Code)

(770) 242-8723

(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, if any, 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 or a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

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 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

As of November 9, 2018, the registrant had 479,249,998 shares of common Stock, \$0.001 par value per share, outstanding.



GUIDED THERAPEUTICS, INC. AND SUBSIDIARY

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**PART I - FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS Unaudited (in Thousands)

ASSETS	September 30, 2018	December 31, 2017
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$70	\$1
Accounts receivable, net of allowance for doubtful accounts of \$157 and \$160 at September 30, 2018 and December 31, 2017, respectively	4	3
Inventory, net of reserves of \$716, at September 30, 2018 and December 31, 2017	265	265
Other current assets	108	111
Total current assets	447	380
Property and equipment, net	27	49
Other assets	17	60
Total noncurrent assets	44	109
<b>TOTAL ASSETS</b>	<b>\$491</b>	<b>\$489</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES:</b>		
Notes payable in default, including related parties	\$609	\$1,091
Short-term note payable, including related parties	620	447
Convertible notes in default	2,354	2,321
Convertible notes payable, net	1,030	783
Accounts payable	2,971	3,019
Accrued liabilities	3,046	4,247
Deferred revenue	35	21
Total current liabilities	10,665	11,929
Warrants at fair value	3,390	7,962
Long-term debt-related parties	606	—
Total long-term debt	3,996	7,962
<b>TOTAL LIABILITIES</b>	<b>14,661</b>	<b>19,891</b>
<b>COMMITMENTS &amp; CONTINGENCIES (Note 7)</b>		
<b>STOCKHOLDERS' DEFICIT:</b>		
	105	355

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Series C convertible preferred stock, \$.001 par value; 9.0 shares authorized, 0.3 and 0.9 shares issued and outstanding as of September 30, 2018 and December 31, 2017, (Liquidation preference of \$286 and \$970 at September 30, 2018 and December 31, 2017, respectively)

Series C1 convertible preferred stock, \$.001 par value; 20.3 shares authorized, 1.0 and 4.3 shares issued and outstanding as of September 30, 2018 and December 31, 2017 (Liquidation preference of \$1,049 and \$4,312 at September 30, 2018 and December 31, 2017, respectively)

Series C2 convertible preferred stock, \$.001 par value; 5,000 shares authorized, 3.3 and nil shares issued and outstanding as of September 30, 2018 and December 31, 2017 (Liquidation preference of \$3,263 and nil at September 30, 2018 and December 31, 2017, respectively)

Common stock, \$.001 Par value; 1,000,000 shares authorized, 384,280 and 49,563 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively

Additional paid-in capital

Treasury stock, at cost

Accumulated deficit

	170	701
	531	—
	1,125	791
	118,914	117,416
	(132 )	(132 )
	(134,883)	(138,533)
TOTAL STOCKHOLDERS' DEFICIT	(14,170 )	(19,402 )

TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$491	\$489
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The accompanying notes are an integral part of these condensed consolidated financial statements.

**GUIDED THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited, in Thousands)**

	FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2018		FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017	
<b>REVENUE:</b>				
Sales – devices and disposables	\$2	\$33	\$15	\$137
Cost of goods sold	—	97	3	195
Gross profit (loss)	2	(64 )	12	(58)
<b>OPERATING EXPENSES:</b>				
Research and development	43	69	175	251
Sales and marketing	39	37	156	187
General and administrative	154	1,169	780	1,894
Total operating expenses	236	1,275	1,111	2,332
Operating loss	(234 )	(1,339)	(1,099 )	(2,390)
<b>OTHER INCOME (EXPENSES):</b>				
Other income	2	3	41	18
Gain from extinguishment of debt	1,039	—	1,039	—
Interest expense	(239 )	(268 )	(795 )	(814 )
Change in fair value of warrants	(1,314 )	(761)	4,572	(359 )
Total other (expenses) income	(512 )	(1,026)	4,857	(3,545 )
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(746 )</b>	<b>(2,365)</b>	<b>3,758</b>	<b>(1,960)</b>
<b>PROVISION FOR INCOME TAXES</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>NET (LOSS) INCOME</b>	<b>(746 )</b>	<b>(2,365)</b>	<b>3,758</b>	<b>3,545 )</b>
<b>PREFERRED STOCK DIVIDENDS</b>	<b>(11 )</b>	<b>(52 )</b>	<b>(108 )</b>	<b>(216 )</b>
	<b>\$(757 )</b>	<b>\$(2,417)</b>	<b>\$3,650</b>	<b>(3,761)</b>



**NET (LOSS) ATTRIBUTABLE TO COMMON  
STOCKHOLDERS**

NET (LOSS) PER SHARE ATTRIBUTABLE TO COMMON  
STOCKHOLDERS

BASIC	\$ (0.002 )	\$ (0.35 )	\$ (0.018 )	(1.43 )
DILUTED	\$ (0.0001 )	\$ (0.35 )	\$ (0.0003 )	(1.43 )

WEIGHTED AVERAGE SHARES OUTSTANDING

BASIC	315,525	6,884	201,231	2,632
DILUTED	8,846,634	6,884	10,988,645	2,632

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

**GUIDED THERAPEUTICS INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited, in Thousands)

	<b>FOR THE NINE MONTHS</b>	
	<b>ENDED</b>	
	<b>SEPTEMBER 30,</b>	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$3,758	\$(3,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt (recovery) expense	1	298
Depreciation	22	77
Amortization of debt issuance costs and discounts	149	196
Stock based compensation	35	56
Change in fair value of warrants	(4,572)	359
Gain on extinguishment of debt	(1,039)	—
Changes in operating assets and liabilities:		
Inventory	1	196
Accounts receivable	(1 )	(89 )
Other current assets	3	80
Other assets	42	300
Accounts payable	(48 )	366
Deferred revenue	14	122
Accrued liabilities	581	1,103
Total adjustments	(4,812)	3,064
Net cash used in operating activities	(1,054)	(481 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from debt financing, net of discounts and debt issuance costs	1,122	746
Payments made on notes and loans payable	(154 )	(205 )
Proceeds for future issuance of common stock	126	—
Proceeds from the issuance of common stock	29	—
Net cash provided by financing activities	1,123	541
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>69</b>	<b>60</b>
<b>CASH AND CASH EQUIVALENTS, beginning of year</b>	<b>1</b>	<b>14</b>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b>\$70</b>	<b>\$74</b>
<b>SUPPLEMENTAL SCHEDULE OF:</b>		
Cash paid for:		

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Interest	\$116	\$1
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock as debt repayment	\$545	\$185
Dividends on preferred stock	\$108	\$216
Capital contributions in connection with debt forgiveness	667	—
Accrued expenses forgiven	1,388	—
Net debt forgiven	369	—

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

## **GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**

### **NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

#### **1. ORGANIZATION, BACKGROUND, AND BASIS OF PRESENTATION**

Guided Therapeutics, Inc. (formerly SpectRx, Inc.), together with its wholly owned subsidiary, InterScan, Inc. (formerly Guided Therapeutics, Inc.), collectively referred to herein as the “Company”, is a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. The Company’s primary focus is the continued commercialization of its LuViva non-invasive cervical cancer detection device and extension of its cancer detection technology into other cancers, including esophageal. The Company’s technology, including products in research and development, primarily relates to biophotonics technology for the non-invasive detection of cancers.

#### **Organization and Background**

All information and footnote disclosures included in the consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

A 1:800 reverse stock split of all the Company’s issued and outstanding common stock was implemented on November 7, 2016. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change. The reverse stock split decreased the Company’s issued and outstanding shares of common stock from 453,694,400 shares to 570,707 shares as of that date. See Note 4, Stockholders’ Deficit. Unless otherwise specified, all per share amounts are reported on a post-stock split basis, as of December 31, 2017. On February 24, 2016, the Company had also implemented a 1:100 reverse stock split of its issued and outstanding common stock.

The Company’s prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. The Company has experienced net losses since its inception and, as of September 30, 2018, it had an accumulated deficit of approximately \$134.9 million. To date, the Company has engaged primarily in research and development efforts and the early stages of marketing its products. The Company may not be successful in growing sales for its products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. The Company’s products may not ever gain market acceptance and the Company may not ever generate significant revenues or achieve profitability. The development and commercialization of the Company’s products requires substantial development, regulatory, sales and marketing, manufacturing and other expenditures. The Company expects operating losses to continue for the foreseeable future as

it continues to expend substantial resources to complete development of its products, obtain regulatory clearances or approvals, build its marketing, sales, manufacturing and finance capabilities, and conduct further research and development.

### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements included herein have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”) for interim financial reporting and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and footnotes required by GAAP for complete financial statements. These statements reflect adjustments, all of which are of a normal, recurring nature, and which are, in the opinion of management, necessary to present fairly the Company’s financial position as of September 30, 2018, results of operations for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results for a full fiscal year. Preparing financial statements requires the Company’s management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities. Actual results could differ from those estimates. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s annual report on Form 10-K for the year ended December 31, 2017.

All information and footnote disclosures included in the consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

## **Going Concern**

The Company's consolidated financial statements have been prepared and presented on a basis assuming it will continue as a going concern. The factors below raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

At September 30, 2018, the Company had a negative working capital of approximately \$10.2 million, accumulated deficit of \$134.9 million, and recognized net income of \$3.7 million (due to the gain in the change in the fair value of warrants and a gain from the extinguishment of debt) for the period then ended. Stockholders' deficit totaled approximately \$14.2 million at September 30, 2018, primarily due to recurring net losses from operations and deemed dividends on warrants and preferred stock, offset by proceeds from the exercise of warrants and proceeds from sales of stock.

The Company's capital-raising efforts are ongoing. If sufficient capital cannot be raised during the fourth quarter of 2018, the Company will continue its plans of curtailing operations by reducing discretionary spending and staffing levels, and attempting to operate by only pursuing activities for which it has external financial support. However, there can be no assurance that such external financial support will be sufficient to maintain even limited operations or that the Company will be able to raise additional funds on acceptable terms, or at all. In such a case, the Company might be required to enter into unfavorable agreements or, if that is not possible, be unable to continue operations, and to the extent practicable, liquidate and/or file for bankruptcy protection.

The Company had warrants exercisable for approximately 3,283.6 million shares of its common stock outstanding at September 30, 2018, with exercise prices ranging between \$0.00046 and \$40,000 per share. Exercise of these warrants would generate a total of approximately \$6.2 million in cash, assuming full exercise, although the Company cannot be assured that holders will exercise any warrants especially given that the majority of the warrants have exercise prices well above the market price of the Company's common stock. Management may obtain additional funds through the public or private sale of debt or equity, and grants, if available. However, please refer to Footnote 10 - CONVERTIBLE DEBT IN DEFAULT in the paragraph: Debt Restructuring for more information regarding our warrants.

## **2. SIGNIFICANT ACCOUNTING POLICIES**

The Company's significant accounting policies were set forth in the audited financial statements and notes thereto for the year ended December 31, 2017 included in its annual report on Form 10-K, filed with the Securities and Exchange Commission ("SEC").

## **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant areas where estimates are used include the allowance for doubtful accounts, inventory valuation and input variables for Black-Scholes, Monte Carlo simulations and binomial calculations. The Company uses the Monte Carlo simulations and binomial calculations in the calculation of the fair value of the warrant liabilities and the valuation of embedded conversion options and freestanding warrants.

### **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of Guided Therapeutics, Inc. and its wholly owned subsidiary. All intercompany transactions are eliminated.

## Accounting Standard Updates

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU 2014-09, “Revenue from Contracts with Distributors (Topic 606),” (“ASU 2014-09”). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with distributors and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model requires revenue recognition to depict the transfer of promised goods or services to distributors in an amount that reflects the consideration a company expects to receive. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from distributor contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU 2015-14, “Deferral of the Effective Date”, which amends ASU 2014-09. As a result, the effective date will be the first quarter of fiscal year 2018 with early adoption permitted in the first quarter of fiscal year 2017. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU 2016-08, “Revenue from Contracts with Distributors (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net),” (“ASU 2016-08”); ASU 2016-10, “Revenue from Contracts with Distributors (Topic 606), Identifying Performance Obligations and Licensing,” (“ASU 2016-10”); ASU 2016-12, “Revenue from Contracts with Distributors (Topic 606) Narrow-Scope Improvements and Practical Expedients,” (“ASU 2016-12”); and ASU 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Distributors,” (“ASU 2016-20”), which are intended to provide additional guidance and clarity to ASU 2014-09. The Company must adopt ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 along with ASU 2014-09 (collectively, the “New Revenue Standards”). The New Revenue Standards may be applied using one of two retrospective application methods: (1) a full retrospective approach for all periods presented, or (2) a modified retrospective approach that presents a cumulative effect as of the adoption date and additional required disclosures. The Company adopted this standard on January 1, 2018, using the modified retrospective method, with no impact on its 2017 financial statements. The cumulative effect of initially applying the new guidance had no impact on its financial statements. However, additional disclosures will be included in future reporting periods in accordance with requirements of the new guidance.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)” that requires lessees to be recognized on the balance sheet with the assets and liabilities associated with the rights and obligations created by those leases. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current U.S. GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as finance or operating lease. The update is effective for reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact adoption of this guidance will have on determination or reporting of its financial results.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments - Credit Losses,” (“ASU 2016-13”). ASU 2016-13 sets forth a “current expected credit loss” model which requires the Company to measure all expected credit losses for



financial instruments held at the reporting date based on historical experience, current conditions and reasonable supportable forecasts. The guidance in this new standard replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. The effective date will be the first quarter of fiscal year 2020. The Company is evaluating the impact that adoption of this new standard will have on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments,” (“ASU 2016-15”). ASU 2016-15 reduces the existing diversity in practice in financial reporting by clarifying existing principles in ASC 230, “Statement of Cash Flows,” and provides specific guidance on certain cash flow classification issues. The effective date for ASU 2016-15 will be the first quarter of fiscal year 2018, with early adoption permitted. The Company adopted this guidance on January 1, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the period ended September 30, 2018.

In November 2016, the FASB issued ASU 2016-18, “Statement of Cash Flows (Topic 230) - Restricted Cash,” (“ASU 2016-18”). ASU 2016-18 requires a statement of cash flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-year and end-of-year total amounts shown on the statement of cash flows. The guidance is effective for annual periods, and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance on January 1, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the period ended September 30, 2018.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718), Scope of Modification Accounting)” (“ASU 2017-09”) which clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance on January 1, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the period ended September 30, 2018.

Except as noted above, the guidance issued by the FASB during the current year is not expected to have a material effect on the Company’s consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”), which aligns the accounting for share-based payment awards issued to employees and non-employees. Under the new guidance, the existing guidance regarding employees will apply to share-based transactions with non-employees, as long as the transaction is not effectively a form of financing, with the exception of specific guidance related to the attribution of compensation cost. The cost of non-employee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for non-employee awards. The Company is evaluating the impact adoption of this guidance will have on determination or reporting of its financial results.

In February 2018, the FASB issued ASU 2018-02, “Income Statement – Reporting Comprehensive Income (Topic 220); Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income”. The amendments in this ASU allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Act. Consequently, the amendments eliminate the stranded tax effects resulting from the Act and will improve the usefulness of information reported to financial statement users. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted in any interim period after issuance of the ASU. The Company does not expect this ASU to have a material impact on its financial statements.

### **Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be a cash equivalent.

## Accounts Receivable

The Company performs periodic credit evaluations of its distributors' financial conditions and generally does not require collateral. The Company reviews all outstanding accounts receivable for collectability on a quarterly basis. An allowance for doubtful accounts is recorded for any amounts deemed uncollectable. The Company does not accrue interest receivable on past due accounts receivable.

## Concentrations of Credit Risk

The Company, from time to time during the years covered by these consolidated financial statements, may have bank balances in excess of its insured limits. Management has deemed this a normal business risk.

## Inventory Valuation

All inventories are stated at lower of cost or net realizable value, with cost determined substantially on a "first-in, first-out" basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when incurred. At September 30, 2018 and December 31, 2017, our inventories were as follows (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	\$ 790	\$ 789
Work in process	81	82
Finished goods	27	27
Consigned inventory	83	83
Inventory reserve	(716 )	(716 )
Total	\$ 265	\$ 265

**Property and Equipment**

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over estimated useful lives of three to seven years. Leasehold improvements are amortized at the shorter of the useful life of the asset or the remaining lease term. Depreciation and amortization expense is included in general and administrative expense on the statement of operations. Expenditures for repairs and maintenance are expensed as incurred. Property and equipment are summarized as follows at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Equipment	\$ 1,378	\$ 1,378
Software	740	740
Furniture and fixtures	124	124
Leasehold Improvement	199	199
	2,441	2,441
Less accumulated depreciation and amortization	(2,414 )	(2,392 )
Total	\$ 27	\$ 49

**Debt Issuance Costs**

Debt issuance costs are capitalized and amortized over the term of the associated debt. Debt issuance costs are presented in the balance sheet as a direct deduction from the carrying amount of the debt liability consistent with the debt discount.

**Other Assets**

Other assets primarily consist of short- and long-term deposits for various tooling inventory that are being constructed for the Company.

**Patent Costs (Principally Legal Fees)**

Costs incurred in filing, prosecuting, and maintaining patents are recurring, and expensed as incurred. Maintaining patents are expensed as incurred as the Company has not yet received U.S. FDA approval and recovery of these costs is uncertain. Such costs aggregated approximately \$11,000 and \$15,000 for the nine months ended September 30, 2018 and 2017, respectively.

### Accrued Liabilities

Accrued liabilities are summarized as follows (in thousands):

	<b>September 30, 2018</b>	December 31, 2017
Accrued compensation	\$ 1,054	\$ 2,122
Accrued professional fees	151	223
Accrued interest	741	511
Accrued warranty	23	39
Accrued vacation	39	152
Accrued dividends	112	291
Stock subscription	402	276
Accrued expenses for licensee	399	429
Other accrued expenses	125	204
Total	\$ 3,046	\$ 4,247

### Revenue Recognition

Revenue from the sale of the Company's products is recognized upon shipment of such products to its distributors. The Company recognizes revenue from contracts on a straight-line basis, over the terms of the contracts. Contracts generally are for shipment of devices and disposables and revenue is recognized once it is transferred to a third-party shipper this is identified in the contract as the performance obligation that has been met.

The Company adopted a new revenue standard on January 1, 2018, using the modified retrospective method with no impact on our financial statements. The cumulative effect of initially adopting the new guidance had no impact on the opening balance of retained earnings as of January 1, 2018. There was no material impact on the condensed consolidated balance sheets as of September 30, 2018 or on the condensed consolidated statements of operations for the three and nine months ended September 30, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new revenue standard, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605.

### **Significant Distributors**

During the nine months ended September 30, 2018, all the Company's revenues were from two distributors and for extended warranty. Revenue from these distributors totaled \$15,000 for the period ended September 30, 2018. Accounts receivable were from one distributor and represents 100% of the balance for the period ended September 30, 2018. During the nine months ended September 30, 2017, there were revenues from four distributors, that totaled approximately \$137,000.

### **Deferred Revenue**

The Company defers payments received as revenue until earned based on the related contracts. As of September 30, 2018, and December 31, 2017, the Company has received prepayments for devices and disposables recorded as deferred revenue in the amount of \$35,000 and \$21,000, respectively.

### **Research and Development**

Research and development expenses consist of expenditures for research conducted by the Company and payments made under contracts with consultants or other outside parties and costs associated with internal and contracted clinical trials. All research and development costs are expensed as incurred.

### **Income Taxes**

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management provides valuation allowances against the deferred tax assets for amounts that are not considered more likely than not to be realized.

The Company is currently delinquent with its federal and applicable state tax return filings, payments and certain Federal and State Unemployment Tax filings. Some of the federal income tax returns are currently under examination by the U.S. Internal Revenue Service (“IRS”). The Company has entered an agreed upon payment plan with the IRS for delinquent payroll taxes. The Company is currently in process of setting up a payment arrangement for its delinquent state income taxes with the State of Georgia and the returns are currently under review by state authorities. Although the Company has been experiencing recurring losses, it is obligated to file tax returns for compliance with IRS regulations and that of applicable state jurisdictions. At December 31, 2017, the Company has approximately \$82.9 million of net operating losses. This net operating loss will be eligible to be carried forward for tax purposes at federal and applicable states level. A full valuation allowance has been recorded related the deferred tax assets generated from the net operating losses.

In 2018, corporate tax rates in the U.S. have decreased from 34% to 21%.

#### Uncertain Tax Positions

The Company assesses each income tax position is assessed using a two-step process. A determination is first made as to whether it is more likely than not that the income tax position will be sustained, based upon technical merits, upon examination by the taxing authorities. If the income tax position is expected to meet the more likely than not criteria, the benefit recorded in the financial statements equals the largest amount that is greater than 50% likely to be realized upon its ultimate settlement. At September 30, 2018 and December 31, 2017, there were no uncertain tax positions.

#### Warrants

The Company has issued warrants, which allow the warrant holder to purchase one share of stock at a specified price for a specified period. The Company records equity instruments including warrants issued to non-employees based on the fair value at the date of issue. The fair value of warrants classified as equity instruments at the date of issuance is estimated using the Black-Scholes Model. The fair value of warrants classified as liabilities at the date of issuance is estimated using the Binomial model.

## **Stock Based Compensation**

The Company records compensation expense related to options granted to non-employees based on the fair value of the award.

Compensation cost is recorded as it is earned for all unvested stock options based upon the grant date fair value estimates, and for compensation cost for all share-based payments granted or modified subsequently based on fair value estimates.

For the nine months ended September 30, 2018 and 2017 share-based compensation for options attributable to employees, officers and Board members were approximately \$35,000 and \$56,000. These amounts have been included in the Company's statements of operations. Compensation costs for stock options which vest over time are recognized over the vesting period. As of September 30, 2018, the Company had approximately \$14,000 of unrecognized compensation costs related to granted stock options that will be recognized over the remaining vesting period of approximately two years.

### **3. FAIR VALUE OF FINANCIAL INSTRUMENTS**

The guidance for fair value measurements, ASC820, Fair Value Measurements and Disclosures, establishes the authoritative definition of fair value, sets out a framework for measuring fair value, and outlines the required disclosures regarding fair value measurements. Fair value is the price that would be received to sell 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 at the measurement date. The Company uses a three-tier fair value hierarchy based upon observable and non-observable inputs as follow:

- Level 1 – Quoted market prices in active markets for identical assets and liabilities;
- Level 2 – Inputs, other than level 1 inputs, either directly or indirectly observable; and
- Level 3 – Unobservable inputs developed using internal estimates and assumptions (there is little or no market data) which reflect those that market participants would use.



The Company records its derivative activities at fair value, which consisted of warrants as of September 30, 2018. The fair value of the warrants was estimated using the Binomial Simulation model. Gains and losses from derivative contracts are included in net gain (loss) from derivative contracts in the statement of operations. The fair value of the Company's derivative warrants is classified as a Level 3 measurement, since unobservable inputs are used in the valuation.

The following table presents the fair value for those liabilities measured on a recurring basis as of September 30, 2018 and December 31, 2017:

**FAIR VALUE MEASUREMENTS (In Thousands)**

The following is summary of items that the Company measures at fair value on a recurring basis:

	<b>Fair Value at September 30, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Warrants issued in connection with Distributor Debt	\$—	\$—	\$(114 )	\$(114 )
Warrants issued in connection with Senior Secured Debt	—	—	(3,275 )	(3,275)
Warrants issued in connection with Short-Term Loans	—	—	(1 )	(1 )
Total long-term liabilities at fair value	\$—	\$—	\$(3,390 )	\$(3,390)

**Fair Value at December 31, 2017**

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Warrants issued in connection with Distributor Debt	\$—	\$—	\$(114 )	\$(114 )
Warrants issued in connection with Senior Secured Debt	—	—	(7,837 )	(7,837)
Warrants issued in connection with Short-Term Loans	—	—	(11 )	(11 )
<b>Total long-term liabilities at fair value</b>	<b>\$—</b>	<b>\$—</b>	<b>\$(7,962 )</b>	<b>\$(7,962)</b>

The following is a summary of changes to Level 3 instruments during the three months ended September 30, 2018:

	<b>Distributor Debt</b>	<b>Short-Term Loan</b>	<b>Senior Secured Debt</b>	<b>Total</b>
Balance, December 31, 2017	\$ (114 )	\$ (11 )	\$(7,837)	\$(7,962)
Change in fair value during the period	—	10	4,562	4,572
Balance, September 30, 2018	\$ (114 )	\$ (1 )	\$(3,275)	\$(3,390)

As of September 30, 2018, the fair value of warrants was approximately \$3.4 million. A net change of approximately \$4.6 million has been recorded to the accompanying statement of operations for the nine months ended September 30, 2018.

**4. STOCKHOLDERS' DEFICIT****Common Stock**

The Company has authorized 1,000,000,000 shares of common stock with \$0.001 par value, of which 384,618,775 were issued and outstanding as of September 30, 2018. As of December 31, 2017, there were 1,000,000,000 authorized shares of common stock, of which 49,562,810 were issued and outstanding.

A 1:800 reverse stock split of all our issued and outstanding common stock was implemented on November 7, 2016. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1

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share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change. On February 24, 2016, the Company had also implemented a 1:100 reverse stock split of its issued and outstanding common stock. The number of the authorized shares did not change.

For the nine months ended September 30, 2018, the Company issued 334,717,651 shares of common stock as listed below:

Series C Preferred Stock Conversions	86,379,038
Series C Preferred Stock Dividends	41,960,315
Equity Financing Conversion	12,600,000
Convertible Debt Conversions	193,778,298
Total	334,771,651

Balance at December 31, 2017	49,562,810
Issued in 2018	334,717,651
Balance at September 30, 2018	384,280,461

On January 22, 2017, the Company entered into a license agreement with Shandong Yaohua Medical Instrument Corporation, or SMI, pursuant to which the Company granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey) and exclusive distribution rights in the Peoples Republic of China, Macau, Hong Kong and Taiwan. In exchange for the license, SMI will pay a \$1.0 million licensing fee, payable in five installments through November 2017, as well as a royalty on each disposable sold in the territories. As of September 30, 2018, SMI had paid \$750,000. SMI will also underwrite the cost of securing approval of LuViva with the Chinese Food and Drug Administration, or CFDA. Pursuant to the SMI agreement, SMI must become capable of manufacturing LuViva in accordance with ISO 13485 for medical devices by the second anniversary of the SMI agreement, or else forfeit the license. Based on the agreement, SMI must purchase no fewer than ten devices (with up to two devices pushed to 2018 if there is a delay in obtaining approval from the CFDA). SMI purchased five devices in 2017 and have not purchased any in 2018. In the three years following CFDA approval, SMI must purchase a minimum of 3,500 devices (500 in the first year, 1,000 in the second, and 2,000 in the third) or else forfeit the license. As manufacturer of the devices and disposables, SMI will be obligated to sell each to us at costs no higher than our current costs. As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue \$1.0 million in shares of its common stock to SMI, in five installments through October 2017, at a price per share equal to the lesser of the average closing price for the five days prior to issuance and \$1.25. These shares have not been issued as of September 30, 2018.

In order to facilitate the SMI agreement, immediately prior to its execution the Company entered into an agreement with Shenghuo Medical, LLC, regarding its previous license to Shenghuo (see Note 7, Commitments and Contingencies). Under the terms of the new agreement, Shenghuo agreed to relinquish its manufacturing license and its distribution rights in SMI's territories, and to waive its rights under the original Shenghuo agreement, all for as long as SMI performs under the SMI agreement. As consideration, the Company agreed to split with Shenghuo the licensing fees and net royalties from SMI that the Company will receive under the SMI agreement. Should the SMI agreement be terminated, the Company have agreed to re-issue the original license to Shenghuo under the original terms. The Company's COO and director, Mark Faupel, is a shareholder of Shenghuo, and another director, Richard Blumberg, is a managing member of Shenghuo.

On July 18, 2018, the Company had exercised its rights under the \$10,000,000 GHS Equity Financing Agreement entered into on March 1, 2018, to exercise puts of \$31,248 for the issuance of 12,600,000 common stock shares. Pursuant to the agreement a put maybe executed for a price that is 80% of the "market price" which is the average of the two lowest volume weighted average prices of the Company's common stock for 15 consecutive trading days preceding the put date.

## **Preferred Stock**

The Company has authorized 5,000,000 shares of preferred stock with a \$.001 par value. The board of directors has the authority to issue these shares and to set dividends, voting and conversion rights, redemption provisions, liquidation preferences, and other rights and restrictions. The board of directors designated 525,000 shares of preferred stock redeemable convertible preferred stock, none of which remain outstanding, 33,000 shares of preferred stock as Series B Preferred Stock, none of which remain outstanding, 9,000 shares of preferred stock as Series C Convertible Preferred Stock, (the "Series C1 Preferred Stock"), of which 327 and 970 were issued and outstanding at September 30, 2018 and December 31, 2017, respectively, and 20,250 shares of preferred stock as Series C1 Preferred Stock, of which 1,050 and 4,312 shares were issued and outstanding at September 30, 2018 and December 31, 2017, respectively.

On August 31, 2018, the Company entered into agreements with certain holders of the Company's Series C1 Preferred Stock, including the chairman of the Company's board of directors, and the Chief Operating Officer and a director of the Company (the "Exchange Agreements"), pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of the Company's newly created Series C2 preferred stock, par value \$0.001 per share (the "Series C2 Preferred Stock"). In total, for 3,262.25 shares of Series C1 Preferred Stock to be surrendered, the Company issued 3,262.25 shares of Series C2 Preferred Stock.

#### ***Series C Convertible Preferred Stock***

On June 29, 2015, the Company entered into a securities purchase agreement with certain accredited investors, including John Imhoff and Mark Faupel, members of the Board, for the issuance and sale of an aggregate of 6,737 shares of Series C convertible preferred stock, at a purchase price of \$750 per share and a stated value of \$1,000 per share. On September 3, 2015 the Company entered into an interim agreement amending the securities purchase agreement to provide for certain of the investors to purchase an additional aggregate of 1,166 shares. Total cash and non-cash expenses were valued at \$853,000, resulting in net proceeds of \$3,698,000.

Pursuant to the Series C certificate of designations, shares of Series C preferred stock are convertible into common stock by their holder at any time and may be mandatorily convertible upon the achievement of specified average trading prices for the Company's common stock. At September 30, 2018, there were 286 shares outstanding with a conversion price of \$0.002624 per share, such that each share of Series C preferred stock would convert into approximately 381,098 shares of the Company's common stock, subject to customary adjustments, including for any accrued but unpaid dividends and pursuant to certain anti-dilution provisions, as set forth in the Series C certificate of designations. The conversion price will automatically adjust downward to 80% of the then-current market price of the Company's common stock 15 trading days after any reverse stock split of the Company's common stock, and 5 trading days after any conversions of the Company's outstanding convertible debt.

Holders of the Series C preferred stock are entitled to quarterly cumulative dividends at an annual rate of 12.0% until 42 months after the original issuance date (the "Dividend End Date"), payable in cash or, subject to certain conditions, the Company's common stock. In addition, upon conversion of the Series C preferred stock prior to the Dividend End Date, the Company will also pay to the converting holder a "make-whole payment" equal to the amount of unpaid dividends through the Dividend End Date on the converted shares. At September 30, 2018, the "make-whole payment" for a converted share of Series C preferred stock would convert to 160,061 shares of the Company's common stock. The Series C preferred stock generally has no voting rights except as required by Delaware law. Upon the Company's liquidation or sale to or merger with another corporation, each share will be entitled to a liquidation preference of \$1,000, plus any accrued but unpaid dividends.

In addition, the purchasers of the Series C preferred stock received, on a pro rata basis, warrants exercisable to purchase an aggregate of approximately 150 shares of Company's common stock. The warrants contain anti-dilution adjustments in the event that the Company issues shares of common stock, or securities exercisable or convertible into shares of common stock, at prices below the exercise price of such warrants. As a result of the anti-dilution protection, the Company is required to account for the warrants as a liability recorded at fair value each reporting period. At September 30, 2018, the exercise price per share was \$640.

On May 23, 2016, an investor canceled certain of these warrants, exercisable into 903 shares of common stock. The same investor also transferred certain of these warrants, exercisable for 150 shares of common stock, to two investors who also had participated in the 2015 Series C financing.

### ***Series C1 Convertible Preferred Stock***

Between April 27, 2016 and May 3, 2016, the Company entered into various agreements with certain holders of Series C preferred stock, including directors John Imhoff and Mark Faupel, pursuant to which those holders separately agreed to exchange each share of Series C preferred stock held for 2.25 shares of the Company's newly created Series C1 Preferred Stock and 12 (9,600 pre-split) shares of the Company's common stock (the "Series C Exchanges"). In connection with the Series C Exchanges, each holder also agreed to roll over the \$1,000 stated value per share of the holder's shares of Series C1 Preferred Stock into the next qualifying financing undertaken by the Company on a dollar-for-dollar basis and, except in the event of an additional \$50,000 cash investment in the Company by the holder, to execute a customary "lockup" agreement in connection with the financing. In total, for 1,916 shares of Series C preferred stock surrendered, the Company issued 4,312 shares of Series C1 Preferred Stock and 22,996 shares of common stock. At September 30, 2018, there were 1,050 shares outstanding with a conversion price of \$0.002624 per share, such that each share of Series C preferred stock would convert into approximately 381,098 shares of the Company's common stock.

On August 31, 2018, 3,262.25 shares of Series C1 Preferred Stock were surrendered, and the Company issued 3,262.25 shares of Series C2 Preferred Stock. At September 30, 2018, shares of Series C2 had a conversion price of \$0.002624 per share, such that each share of Series C preferred stock would convert into approximately 381,098 shares of the Company's common stock.

The Series C1 preferred stock has terms that are substantially the same as the Series C preferred stock, except that the Series C1 preferred stock does not pay dividends (unless and to the extent declared on the common stock) or at-the-market "make-whole payments" and, while it has the same anti-dilution protections afforded the Series C preferred stock, it does not automatically reset in connection with a reverse stock split or conversion of our outstanding convertible debt.

**Series C2 Convertible Preferred Stock**

On August 31, 2018, the Company entered into agreements with certain holders of the Company's Series C1 Preferred Stock, including the chairman of the Company's board of directors, and the Chief Operating Officer and a director of the Company pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of the Company's newly created Series C2 Preferred Stock. In total, for 3,262.25 shares of Series C1 Preferred Stock to be surrendered, the Company issued 3,262.25 shares of Series C2 Preferred Stock.

The terms of the Series C2 Preferred Stock are substantially the same as the Series C1 Preferred Stock, except that (i) shares of Series C1 Preferred Stock may not be convertible into the Company's common stock by their holder for a period of 180 days following the date of the filing of the Certificate of Designation (the "Lock-Up Period"); (ii) the Series C2 Preferred Stock has the right to vote as a single class with the Company's common stock on an as-converted basis, notwithstanding the Lock-Up Period; and (iii) the Series C2 Preferred Stock will automatically convert into that number of securities sold in the next Qualified Financing (as defined in the Exchange Agreement) determined by dividing the stated value (\$1,000 per share) of such share of Series C2 Preferred Stock by the purchase price of the securities sold in the Qualified Financing.

**Warrants**

The following table summarizes transactions involving the Company's outstanding warrants to purchase common stock for the nine months ended September 30, 2018:

	<b>Warrants (Underlying Shares)</b>
Outstanding, January 1, 2018	294,089,138
Issuances	2,989,526,619
Canceled / Expired	(49 )
Exercised	—
Outstanding, September 30, 2018	3,283,615,708

The Company had the following shares reserved for the warrants as of September 30, 2018:

<b>Warrants (Underlying Shares)</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
7,542	(1) \$75.00 per share	June 14, 2021
3	(2) \$40,000.00 per share	April 23, 2019
8	(3) \$36,000.00 per share	May 22, 2019
3	(4) \$30,400.00 per share	September 10, 2019
5	(5) \$36,864.80 per share	September 27, 2019
10	(6) \$22,504.00 per share	December 2, 2019
105	(7) \$7,200.00 per share	December 2, 2020
105	(8) \$8,800.00 per share	December 2, 2020



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22	(9) \$9,504.00 per share	June 29, 2020
362	(9) \$640.00 per share	September 21, 2020
659	(10) \$640.00 per share	June 29, 2020
343	(11) \$640.00 per share	September 4, 2020
7	(12) \$9,504.00 per share	September 4, 2020
198	(13) \$640.00 per share	October 23, 2020
7	(14) \$9,504.00 per share	October 23, 2020
3,125,000,000	(15) \$0.00046 per share	June 14, 2021
150,000,000	(16) \$0.00046 per share	February 21, 2021
17,239	(17) \$13.92 per share	June 6, 2021
200,000	(18) \$0.00228 per share	February 13, 2022
20,000	(19) \$0.18 per share	May 16, 2022
550,000	(20) \$0.019 per share	November 16, 2020
200,000	(21) \$0.029 per share	December 28, 2020
1,500,000	(22) \$0.0201 per share	January 10, 2021
60,000	(23) \$0.011 per share	March 19, 2021
3,409,090	(24) \$0.00228 per share	March 20, 2021
50,000	(25) \$0.06 per share	April 30, 2021
400,000	(26) \$0.06 per share	May 17, 2021
100,000	(27) \$0.06 per share	May 25, 2021
100,000	(28) \$0.06 per share	June 1, 2021
1,500,000	(29) \$0.25 per share	August 22, 2021
500,000	(30) \$0.25 per share	September 18, 2021
<b>3,283,615,708*</b>		

\* However, please refer to *Footnote 10 - CONVERTIBLE DEBT IN DEFAULT* in the paragraph: Debt Restructuring for more information regarding our warrants.

- (1) Issued in June 2015 in exchange for warrants originally issued as part of a May 2013 private placement. Issued to a placement agent in conjunction with an April 2014 private placement. Issued to a placement agent in conjunction with a September 2014 private placement.
- (2) Issued as part of a September 2014 Regulation S offering. Issued to a placement agent in conjunction with a 2014 public offering.
- (3) Issued in June 2015 in exchange for warrants originally
- (4)
- (5)
- (6)

- issued as part of a 2014 public offering.
- (7) Issued as part of a March 2015 private placement.
- (8) Issued to a placement agent in conjunction with a June 2015 private placement.
- (9) Issued as part of a June 2015 private placement.
- (10) Issued as part of a June 2015 private placement.
- (11) Issued as part of a June 2015 private placement.
- (12) Issued to a placement agent in conjunction with a June 2015 private placement.
- (13) Issued as part of a June 2015 private placement.
- (14) Issued to a placement agent in conjunction with a June 2015 private placement.
- (15)

- Issued as part of a February 2016 private placement.
- (16) Issued to a placement agent in conjunction with a February 2016 private placement.
- (17) Issued pursuant to a strategic license agreement.
- (18) Issued as part of a February 2017 private placement.
- (19) Issued as part of a May 2017 private placement.
- (20) Issued to investors for a loan in November 2017.
- (21) Issued to investors for a loan in December 2017.
- (22) Issued to investors for a loan in January 2018.
- (23) Issued to investors for a loan in March 2018.
- (24) Issued to investors for

- a loan in  
March  
2018.  
Issued to  
(25) investors for  
a loan in  
April 2018.  
Issued to  
(26) investors for  
a loan in  
May 2018.  
Issued to  
(27) investors for  
a loan in  
May 2018.  
Issued to  
(28) investors for  
a loan in  
June 2018  
Issued to  
(29) investors for  
a loan in  
August  
2018  
Issued to  
(30) investors for  
a loan in  
September  
2018

All outstanding warrant agreements provide for anti-dilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other changes in the Company's corporate structure; except for (8). In addition, warrants subject to footnotes (1) and (9)-(11), (13), and (15) – (30) in the table above are subject to "lower price issuance" anti-dilution provisions that automatically reduce the exercise price of the warrants (and, in the cases of warrants subject to footnote (1), (15) and (16) in the table above, increase the number of shares of common stock issuable upon exercise), to the offering price in a subsequent issuance of the Company's common stock, unless such subsequent issuance is exempt under the terms of the warrants.

For the warrants to footnote (15), the Company further agreed to amend the warrant issued with the original senior secured convertible note, to adjust the number of shares issuable upon exercise of the warrant to equal the number of shares that will initially be issuable upon conversion of the new convertible note (without giving effect to any beneficial ownership limitations set forth in the terms of the new convertible note).

The warrants subject to footnote (1) are subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations, to require exercise of such warrants at any time following (a) the date that is the 30th day after the later of the Company's receipt of an approvable letter from the U.S. FDA for LuViva and the date on which the common stock achieves an average market price for 20 consecutive trading days of at least \$1,040.00 with an average daily trading volume during such 20 consecutive trading days of at least 250 shares, or (b) the date on which the average market price of the common stock for 20 consecutive trading days immediately prior to the date the Company delivers a notice demanding exercise is at least \$129,600.00 and the average daily trading volume of the common stock exceeds 250 shares for such 20 consecutive trading days. If these warrants are not timely

exercised upon demand, they will expire. Upon the occurrence of certain events, the Company may be required to repurchase these warrants, as well as the warrants subject to footnote (1) in the table above.

The warrants subject to footnote (4) in the table above are also subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations; to require the exercise of such warrants should the average trading price of its common stock over any 30-consecutive day trading period exceed \$92.16.

The warrants subject to footnote (6) in the table above are also subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations, to require exercise of 50% of the then-outstanding warrants if the trading price of its common stock is at least two times the initial warrant exercise price for any 20-day trading period. Further, in the event that the trading price of the Company's common stock is at least 2.5 times the initial warrant exercise price for any 20-day trading period, the Company will have the right to require the immediate exercise of 50% of the then-outstanding warrants. Any warrants not exercised within the prescribed time periods will be canceled to the extent of the number of shares subject to mandatory exercise.

The holders of the warrants subject to footnote (1) in the table above have agreed to surrender the warrants, upon consummation of a qualified public financing, for new warrants exercisable for 200% of the number of shares underlying the surrendered warrants, but without certain anti-dilution protections included with the surrendered warrants.

### **Series B Tranche B Warrants**

As discussed in Note 3, Fair Value Measurements, between June 13, 2016 and June 14, 2016, the Company entered into various agreements with holders of the Company's "Series B Tranche B" warrants, pursuant to which each holder separately agreed to exchange the warrants for either (1) shares of common stock equal to 166% of the number of shares of common stock underlying the surrendered warrants, or (2) new warrants exercisable for 200% of the number of shares underlying the surrendered warrants, but without certain anti-dilution protections included with the surrendered warrants. In total, for surrendered warrants then-exercisable for an aggregate of 1,185,357 shares of common stock (but subject to exponential increase upon operation of certain anti-dilution provisions), the Company issued or is obligated to issue 16,897 shares of common stock and new warrants that, if exercised as of the date hereof, would be exercisable for an aggregate of 216,707 shares of common stock. As of September 30, 2018, the Company had issued 14,766 shares of common stock and rights to common stock shares for 2,131. In certain circumstances, in lieu of presently issuing all of the shares (for each holder that opted for shares of common stock), the Company and the holder further agreed that the Company will, subject to the terms and conditions set forth in the applicable warrant exchange agreement, from time to time, be obligated to issue the remaining shares to the holder. No additional consideration will be payable in connection with the issuance of the remaining shares. The holders that elected to receive shares for their surrendered warrants have agreed that they will not sell shares on any trading day in an amount, in the aggregate, exceeding 20% of the composite aggregate trading volume of the common stock for that trading day. The holders that elected to receive new warrants will be required to surrender their old warrants upon consummation of the Company's next financing resulting in net cash proceeds to the Company of at least \$1 million. The new warrants will have an initial exercise price equal to the exercise price of the surrendered warrants as of immediately prior to consummation of the financing, subject to customary "downside price protection" for as long as the Company's common stock is not listed on a national securities exchange, and will expire five years from the date of issuance.

## **5. STOCK OPTIONS**

The Company's 1995 Stock Plan (the "Plan") has expired pursuant to its terms, so zero shares remained available for issuance at September 30, 2018. The Plan allowed for the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options was determined by the Company's board of directors, but incentive stock options were granted at an exercise price equal to the fair market value of the Company's common stock as of the grant date. Options historically granted have generally become exercisable after four years and expire ten years from the date of grant.

As of September 30, 2018, the Company has issued and outstanding options to purchase a total of 116 shares of common stock pursuant to the Plan, at a weighted average exercise price of \$37,090 per share.

The fair value of stock options is estimated using the Black-Scholes option pricing model. No options were issued during the period ended September 30, 2018.



Stock option activity for September 30, 2018 as follows:

	<b>2018</b>	<b>Weighted Average Exercise Price</b>
	<b>Shares</b>	
Outstanding at beginning of year	<b>118</b>	<b>\$ 37,090</b>
Options granted	-	\$-
Options exercised	-	\$-
Options expired/forfeited	<b>(2 )</b>	<b>\$ 37,090</b>
Outstanding at end of the period	<b>116</b>	<b>\$ 37,090</b>

## 6. LITIGATION AND CLAIMS

From time to time, the Company may be involved in various legal proceedings and claims arising in the ordinary course of business. Management believes that the dispositions of these matters, individually or in the aggregate, are not expected to have a material adverse effect on the Company's financial condition. However, depending on the amount and timing of such disposition, an unfavorable resolution of some or all of these matters could materially affect the future results of operations or cash flows in a particular period.

As of September 30, 2018, and December 31, 2017, there was no accrual recorded for any potential losses related to pending litigation.

## 7. COMMITMENTS AND CONTINGENCIES

### Operating Leases

In December 2009, the Company moved its offices, which comprise its administrative, research and development, marketing and production facilities to 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092. The Company leased approximately 23,000 square feet under a lease that expired in June 2017. In July 2017, the Company leased the offices on a month to month basis. On February 23, 2018, the Company modified its lease to reduce its occupancy

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to 12,835 square feet. The fixed monthly lease expense will be: \$13,859 each month for the period beginning January 1, 2018 and ending March 31, 2018; \$8,022 each month for the period beginning April 1, 2018 and ending March 31, 2019; \$8,268 each month for the period beginning April 1, 2019 and ending March 31, 2020; and \$8,514 each month for the period beginning April 1, 2020 and ending March 31, 2021. The Company recognizes rent expense on a straight-line basis over the estimated lease term. Future minimum rental payments at September 30, 2018 under non-cancellable operating leases for office space and equipment are as follows (in thousands):

Year	Amount
2018	28
2019	98
2020	101
2021	26

## Related Party Contracts

On June 5, 2016, the Company entered into a license agreement with Shenghuo Medical, LLC pursuant to which the Company granted Shenghuo an exclusive license to manufacture, sell and distribute LuViva in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. Shenghuo was already the Company's exclusive distributor in China, Macau and Hong Kong, and the license extended to manufacturing in those countries as well. Under the terms of the license agreement, once Shenghuo was capable of manufacturing LuViva in accordance with ISO 13485 for medical devices, Shenghuo would pay the Company a royalty equal to \$2.00 or 20% of the distributor price (subject to a discount under certain circumstances), whichever is higher, per disposable distributed within Shenghuo's exclusive territories. In connection with the license grant, Shenghuo was to underwrite the cost of securing approval of LuViva with Chinese Food and Drug Administration. At its option, Shenghuo also would provide up to \$1.0 million in furtherance of the Company's efforts to secure regulatory approval for LuViva from the U.S. Food and Drug Administration, in exchange for the right to receive payments equal to 2% of the Company's future sales in the United States, up to an aggregate of \$4.0 million. Pursuant to the license agreement, Shenghuo had the option to have a designee appointed to the Company's board of directors (director Richard Blumberg is that designee). As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue a convertible note to Shenghuo, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to Shenghuo of \$300,000, expected to be due the earlier of 90 days from issuance and consummation of any capital raising transaction by the Company with net cash proceeds of at least \$1.0 million. The note will accrue interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of the Company's common stock at a conversion price per share of \$13.92, subject to customary anti-dilution adjustment. The note will be unsecured, and is expected to provide for customary events of default. The Company will also issue Shenghuo a five-year warrant exercisable immediately for approximately 21,549 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment. On January 22, 2017, the Company entered into a license agreement with Shandong Yaohua Medical Instrument Corporation, or SMI, pursuant to which the Company granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey) and exclusive distribution rights in the Peoples Republic of China, Macau, Hong Kong and Taiwan. In order to facilitate the SMI agreement, immediately prior to its execution the Company entered into an agreement with Shenghuo Medical, LLC, regarding its previous license to Shenghuo. Under the terms of the new agreement, Shenghuo agreed to relinquish its manufacturing license and its distribution rights in SMI's territories, and to waive its rights under the original Shenghuo agreement, all for as long as SMI performs under the SMI agreement.

On September 6, 2016, the Company entered into a royalty agreement with one of its directors, John Imhoff, and another stockholder, Dolores Maloof, pursuant to which the Company sold to them a royalty of future sales of single-use cervical guides for LuViva. Under the terms of the royalty agreement, and for consideration of \$50,000, the Company will pay them an aggregate perpetual royalty initially equal to \$0.10, and from and after October 2, 2016, equal to \$0.20, for each disposable that the Company sells (or that is sold by a third party pursuant to a licensing arrangement with the Company).

## 8. NOTES PAYABLE

### **Notes Payable in Default**

At September 30, 2018 and December 31, 2017, the Company maintained notes payable and accrued interest to both related and non-related parties totaling \$609,468 and \$1,091,000, respectively. These notes are short term, straight-line amortizing notes. The notes carry annual interest rates between 5% and 10% and have default rates as high as 18.0%. The Company is accruing interest at the default rate of 18.0% on two of the loans. As of September 30, 2018, there have been no principal or interest payments.

### **Short Term Notes Payable**

At September 30, 2018 and December 31, 2017, the Company maintained short term notes payable and accrued interest to both related and non-related parties totaling \$378,000 and \$354,000, respectively. These notes are short term, straight-line amortizing notes. The notes carry annual interest rates between 5% and 18%.

In July 2018, the Company entered into a premium finance agreement to finance its insurance policies totaling \$126,928. The note requires monthly payments of \$12,711, including interest at 4.91% and matures in May 2019. As of September 30, 2018, a balance of \$87,899 remained. The balance due on insurance policies totaled \$93,000 at December 31, 2017.

On August 22, 2018, the Company issued a promissory note to an investor for \$150,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$157,500 (representing a \$7,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received by the Company from a financing of at least \$2,000,000, or at the option of the investor, to be included in the Company's financing under the same terms as the new investors with the most favorable terms making a cash investment. If the Company does not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 1,500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing of the Company or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of September 30, 2018, the Company had not repaid the note.

On September 6, 2018, the Company issued a promissory note to an investor for \$50,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$52,500 (representing a \$2,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received by the Company from a financing of at least \$2,000,000, or at the option of the investor, to be included in the Company's financing under the same terms as the new investors with the most favorable terms making a cash investment. If the Company does not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing of the Company or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of September 30, 2018, the Company had not repaid the note of \$153,600.

## **9. SHORT-TERM CONVERTIBLE DEBT**

### **Related Party Convertible Note Payable – Short-Term**

On June 5, 2016, the Company entered into a license agreement with a distributor pursuant to which the Company granted the distributor an exclusive license to manufacture, sell and distribute the Company's LuViva Advanced Cervical Cancer device and related disposables in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. The distributor was already the Company's exclusive distributor in China, Macau and Hong Kong, and the license will extend to manufacturing in those countries as well.

As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue a convertible note to the distributor, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to the distributor of \$240,000, due upon consummation of any capital raising transaction by the Company within 90 days and with net cash proceeds of at least \$1.0 million. As of September 30, 2018, the Company had a note due of \$397,413 compared to a note due of \$417,160 for the period ended December 31, 2017. The note accrues interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of the Company's common stock at a conversion price per share of \$13.92, subject to customary anti-dilution adjustment. The note is unsecured, and is expected to provide for customary events of default. The Company will also issue the distributor a five-year warrant exercisable immediately for 17,239 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment.

### **Convertible Note Payable – Short-Term**

On February 13, 2017, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$170,000 in aggregate principal amount of a 12% convertible promissory note for an aggregate purchase price of \$156,400 (representing a \$13,600 original issue discount). On February 13, 2017, the Company issued the note to Auctus. Pursuant to the purchase agreement, the Company also issued to Auctus a warrant exercisable to purchase an aggregate of 200,000 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$0.00228 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matured nine months from the date of issuance and, in addition to the original issue discount, accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus converted the note, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus required the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. In connection with the transaction, the Company agreed to reimburse Auctus for \$30,000 in legal and diligence fees, of which we paid \$10,000 in cash and \$20,000 in restricted shares of common stock, valued at \$0.40 per share (a 42.86% discount to the closing price of the common stock on the day prior to issuance). The Company allocated proceeds of \$90,000 to the warrants and common stock issued in connection with the financing. As of September 30, 2018, the notes had been converted and no balance remained outstanding as compared to net debt and accrued interest of \$76,664 for the period ended December 31, 2017.

On March 20, 2018, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$150,000 in aggregate principal amount of a 12% convertible promissory note. On March 20, 2018, the Company issued the note to Auctus. Pursuant to the purchase agreement, the Company also issued to Auctus a warrant exercisable to purchase an aggregate of 3,409,090 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$0.00228 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matures nine months from the date of issuance and accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of September 30, 2018, the Company has net debt of \$134,573 including unamortized debt issuance costs of \$9,607 as well as a reduction related to the allocated value of the warrants of \$5,820 and accrued interest of \$9,700.

On July 3, 2018, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$89,250 in aggregate principal amount of a 12% convertible promissory note. On July 3 2018, the Company issued the note to Auctus. The note matures nine months from the date of issuance and accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of September 30, 2018, the Company has net debt of \$73,889, including unamortized original issue discount of \$2,870, unamortized debt issuance costs of \$12,491 and accrued interest of \$2,648.

On May 17, 2017, the Company entered into a securities purchase agreement with Eagle Equities, LLC ("Eagle"), providing for the purchase by Eagle of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which the Company received \$40,000 of net proceeds (net of a

10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Eagle. Eagle was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note the Company issued. The notes bear an interest rate of 8%, and were due and payable on May 17, 2018. The notes may be converted by Eagle at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes was equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company received a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of September 30, 2018, the notes had been converted and no balance remained outstanding, as compared to net debt of \$41,322, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160 for the period ended December 31, 2017.



On March 12, 2018, the Company entered into a securities purchase agreement with Eagle Equities, LLC, providing for the purchase by Eagle of a convertible redeemable note in the principal amount of \$66,667. The note was fully funded on March 14, 2018, upon which the Company received \$51,000 of net proceeds (net of a 10% original issue discount and other expenses). The note bears an interest rate of 8%, and are due and payable on May 12, 2019. The note may be converted by Eagle at any time after twelve months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of September 30, 2018, the outstanding balance was \$59,670, including unamortized debt issuance costs of \$4,019, and unamortized discount of \$2,977 and accrued interest of \$2,952.

On May 17, 2017, the Company entered into a securities purchase agreement with Adar Bays, LLC("Adar"), providing for the purchase by Adar of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which the Company received \$40,000 of net proceeds (net of a 10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Adar. Adar was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note the Company issued. The notes bear an interest rate of 8%, and were due and payable on May 17, 2018. The notes may be converted by Adar at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of September 30, 2018, the notes had been converted and no balance remained outstanding, as compared to net debt of \$42,216, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160 for the period ended December 31, 2017.

On February 12, 2018, the Company entered into a securities purchase agreement with Adar Bays, LLC, providing for the purchase by Adar of three convertible redeemable notes in the aggregate principal amount of \$285,863, with the first note being in the amount of \$95,288, and the second and third note being in the same amount. The first note was fully funded on February 13, 2018, upon which the Company received \$75,000 of net proceeds (net of a 10% original issue discount). The notes bear an interest rate of 8%, and are due and payable on October 12, 2018. The notes may be

converted by Adar at any time after eight months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of September 30, 2018, the Company has a net debt of \$69,761, including unamortized debt issuance costs of \$576, and unamortized discount of \$430 and accrued interest of \$3,617.

On May 18, 2017, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$66,000, for \$60,000 in net proceeds (representing a 10% original issue discount). The transaction closed on May 19, 2017. The note matures upon the earlier of our receipt of \$100,000 from revenues, loans, investments, or any other means (other than the Eagle and Adar bridge financings) and December 31, 2017. In addition to the 10% original issue discount, the note accrues interest at a rate of 8% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 60% of the lowest trading price during the 25 trading days prior to conversion. The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of September 30, 2018, the Company has net debt of \$66,000 and accrued interest of \$13,842 as compared to net debt of \$66,000 for the period ended December 31, 2017.

On May 17, 2018, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$9,250 (with \$750 representing a 10% original issue discount and \$1,000 for transaction costs). The note matures on June 17, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of September 30, 2018, the Company has net debt of \$8,101, including unamortized debt issuance costs of \$657, and unamortized discount of \$492.

On June 22, 2018, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$68,000 (with \$6,000 representing a 10% original issue discount and \$2,000 for transaction costs). The note matures on June 22, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of September 30, 2018, the Company has net debt of \$58,562, including unamortized debt costs of \$9,438 and accrued interest of \$1,863.

On August 18, 2017, the Company entered into a securities purchase agreement with Power Up Lending Group Ltd. ("Power Up"), providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on May 19, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the notes had been

converted and no balance remained outstanding as compared to a net debt of \$46,405, including unamortized debt issuance costs of \$6,595 of December 31, 2017.

On October 12, 2017, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on July 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the note had been converted and no balance remained outstanding, as compared to net debt of \$47,288, including unamortized debt issuance costs of \$5,722 for the period ended December 31, 2017.

On December 11, 2017, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on September 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the note had been converted and no balance remained outstanding, as compared to net debt of \$45,565, including unamortized debt issuance costs of \$7,435 for the period ended December 31, 2017.

On February 22, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on November 30, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the note had been converted and no balance remained outstanding.

On April 30, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$103,000. The note bears an interest rate of 12% and is due and payable on February 15, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the Company has net debt of \$96,835, including unamortized debt issuance cost of \$6,165 and accrued interest of \$5,181.

On June 7, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12% and is due and payable on March 30, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to

conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of September 30, 2018, the Company has net debt of \$48,108, including unamortized debt issuance cost of \$4,892 and accrued interest of \$2,004.

On December 28, 2016, the Company entered into a securities purchase agreement with an investor for the issuance and sale to investor of up to \$330,000 in aggregate principal amount of 10% original issuance discount convertible promissory notes, for an aggregate purchase price of \$300,000. On that date, the Company issued to the investor a note in the principal amount of \$222,000, for a purchase price of \$200,000. The note matures nine months from their date of issuance and, in addition to the 10% original issue discount, accrue interest at a rate of 10% per year. The Company may prepay the notes, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance until immediately prior to the maturity date. After nine months from the date of issuance (i.e., if the Company fails to repay all principal and interest due under the notes at the maturity date), the investor may convert the notes, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to 60% of the lowest volume weighted average price of our common stock during the 20 trading days prior to conversion, subject to certain customary adjustments and anti-dilution provisions contained in the note. As of September 30, 2018, the Company has fully amortized debt issuance costs \$30,000 and original issue discount of \$22,000. As of September 30, 2018, the balance due to the investor for the December 28, 2016 note, is \$413,852.

The total amount attributed to short-term convertible debt is \$1,030,000 and \$783,000, for the periods ended September 30, 2018 and December 31, 2017.

## 10. CONVERTIBLE DEBT IN DEFAULT

### Secured Promissory Note.

On September 10, 2014, the Company sold a secured promissory note to an accredited investor with an initial principal amount of \$1,275,000, for a purchase price of \$700,000 (an original issue discount of \$560,000). The Company may prepay the note at any time. The note is secured by the Company's current and future accounts receivable and inventory, pursuant to a security agreement entered into in connection with the sale. On March 10, 2015, May 4, 2015, June 1, 2015, June 16, 2015, June 29, 2015, January 21, 2016, January 29, 2016, and February 12, 2016 the Company amended the terms of the note to extend the maturity ultimately until August 31, 2016. During the extension, interest accrues on the note at a rate of the lesser of 18% per year or the maximum rate permitted by applicable law. On February 11, 2016, the Company consented to an assignment of the note to two accredited investors. In connection with the assignment, the holders waived an ongoing event of default under the notes related to the Company's minimum market capitalization and agreed to eliminate the requirement going forward. Pursuant to the terms of the amended note, the holder may convert the outstanding balance into shares of common stock at a conversion price per share equal to the lower of (1) \$25.00 or (2) 75% of the lowest daily volume weighted average price of the common stock during the five days prior to conversion. If the conversion price at the time of any conversion is lower than \$15.00, the Company has the option of delivering the conversion amount in cash in lieu of shares of common stock. On March 7, 2016, the Company further amended the note to eliminate the volume limitations on sales of common stock issued or issuable upon conversion. On July 13, 2016, the Company consented to the assignment by one of the accredited investors of its portion of the note of to a third accredited investor.

The balance due on the note was \$155,552 and \$184,245 at September 30, 2018 and December 31, 2017, respectively. The balance was reduced by \$306,863 as part of a debt restructuring on December 7, 2016.

Total debt issuance costs as originally capitalized were approximately \$130,000. This amount was amortized over nine months and was fully amortized as of December 31, 2015. The original issue discount of \$560,000 was fully amortized as of December 31, 2015.

On November 2, 2016, the Company entered into a lockup and exchange agreement with GHS Investments, LLC, holder of approximately \$221,000 in outstanding principal amount of the Company's secured promissory note and all the outstanding shares of the its Series C preferred stock. Pursuant to the agreement, upon the effectiveness of the 1:800 reverse stock split and continuing for 45 days after, GHS and its affiliates were prohibited from converting any portion of the secured promissory note or any of the shares of Series C preferred stock or selling any of the Company's securities that they beneficially owned. The Company agreed that, upon consummation of its next financing, the Company would use \$260,000 of net cash proceeds first, to repay GHS's portion of the secured promissory note and

second, with any remaining amount from the \$260,000, to repurchase a portion of GHS's shares of Series C preferred stock. In addition, GHS has agreed to exchange the stated value per share (plus any accrued but unpaid dividends) of its remaining shares of Series C preferred stock for new securities of the same type that the Company separately issue in the next qualifying financing it undertakes, on a dollar-for-dollar basis in a private placement exchange.



**Senior Secured Promissory Note**

On February 11, 2016, the Company entered into a securities purchase agreement with GPB Debt Holdings II LLC for the issuance and sale on February 12, 2016 of \$1.4375 million in aggregate principal amount of a senior secured convertible note for an aggregate purchase price of \$1.15 million (a 20% original issue discount of \$287,500) and a discount for debt issuance costs paid at closing of \$121,000 for a total of \$408,500. In addition, GPB received a warrant exercisable to purchase an aggregate of approximately 2,246 shares of the Company's common stock. The Company allocated proceeds totaling \$359,555 to the fair value of the warrants at issuance. This was recorded as an additional discount on the debt. The convertible note matures on the second anniversary of issuance and, in addition to the 20% original issue discount, accrues interest at a rate of 17% per year. The Company is required to pay monthly interest coupons and beginning nine months after issuance, the Company is required to pay amortized quarterly principal payments. If the Company does not receive, on or before the first anniversary after issuance, an aggregate of at least \$3.0 million from future equity or debt financings or non-dilutive grants, then the holder will have the option of accelerating the maturity date to the first anniversary of issuance. The Company may prepay the convertible note, in whole or in part, without penalty, upon 20 days' prior written notice. Subject to resale restrictions under Federal securities laws and the availability of sufficient authorized but unissued shares of the Company's common stock, the convertible note is convertible at any time, in whole or in part, at the holder's option, into shares of the Company's common stock, at a conversion price equal to the lesser of \$0.80 per share or 70% of the average closing price per share for the five trading days prior to issuance, subject to certain customary adjustments and anti-dilution provisions contained in the convertible note. On May 28, 2016, in exchange for an additional \$87,500 in cash from GPB to the Company, the principal balance was increased by the same amount. The Company is currently in default as they are past due on the required monthly interest payments. In the event of default, the Company shall accrue interest at a rate the lesser of 22% or the maximum permitted by law. The Company has accrued \$117,000 for past due interest payments at December 31, 2016. Upon the occurrence of an event of default, the holder may require the Company to redeem the convertible note at 120% of the outstanding principal balance (but as of September 30, 2018, had not done so). As of September 30, 2018, the balance due on the convertible debt was \$2,198,236 as the Company has fully amortized debt issuance costs of \$47,675 and the debt discount of \$768,055 and recorded a 20% penalty totaling \$366,373. In addition, the Company has accrued \$498,910 of interest expense. As of December 31, 2017, the balance due on the convertible debt was \$2,136,863 as the Company has fully amortized debt issuance costs of \$47,675 and the debt discount of \$768,055 and recorded a 20% penalty totaling \$305,000. In addition, the Company has accrued \$596,751 of interest expense. The convertible note is secured by a lien on all the Company's assets, including its intellectual property, pursuant to a security agreement entered into by the Company and GPB.

The warrant is exercisable at any time, pending availability of sufficient authorized but unissued shares of the Company's common stock, at an exercise price per share equal to the conversion price of the convertible note, subject to certain customary adjustments and anti-dilution provisions contained in the warrant. The warrant has a five-year term. As of September 30, 2018, the exercise price had been adjusted to \$0.00046 and the number of common stock shares exchangeable for was 3,125,000,000. As of September 30, 2018, the effective interest rate considering debt costs was 29%.

The Company used a placement agent in connection with the transaction. For its services, the placement agent received a cash placement fee equal to 4% of the aggregate gross proceeds from the transaction and a warrant to purchase shares of common stock equal to an aggregate of 6% of the total number of shares underlying the securities sold in the transaction, at an exercise price equal to, and terms otherwise identical to, the warrant issued to the investor. Finally, the Company agreed to reimburse the placement agent for its reasonable out-of-pocket expenses.

In connection with the transaction, on February 12, 2016, the Company and GPB entered into a four-year consulting agreement, pursuant to which the investor will provide management consulting services to the Company in exchange for a royalty payment, payable quarterly, equal to 3.5% of the Company's revenues from the sale of products. As of September 30, 2018, and December 31, 2017, GPB had earned approximately \$29,000 in royalties.

### **Debt Restructuring**

On December 7, 2016, the Company entered into an exchange agreement with GPB with regard to the \$1,525,000 in outstanding principal amount of senior secured convertible note originally issued to GPB on February 11, 2016, and the \$306,863 in outstanding principal amount of the Company's secured promissory note that GPB holds (see "—Secured Promissory Note"). Pursuant to the exchange agreement, upon completion of the next financing resulting in at least \$1 million in cash proceeds, GPB will exchange both securities for a new convertible note in principal amount of \$1,831,863. The new convertible note will mature on the second anniversary of issuance and will accrue interest at a rate of 19% per year. The Company will pay monthly interest coupons and, beginning one year after issuance, will pay amortized quarterly principal payments. Subject to resale restrictions under Federal securities laws and the availability of sufficient authorized but unissued shares of the Company's common stock, the new convertible note will be convertible at any time, in whole or in part, at the holder's option, into shares of common stock, at a conversion price equal to the price offered in the qualifying financing that triggers the exchange, subject to certain customary adjustments and anti-dilution provisions contained in the new convertible note. The new convertible note will include customary event of default provisions and a default interest rate of the lesser of 21% or the maximum amount permitted by law. Upon the occurrence of an event of default, GPB will be entitled to require the Company to redeem the new convertible note at 120% of the outstanding principal balance. The new convertible note will be secured by a lien on all the Company's assets, including its intellectual property, pursuant to the security agreement entered into by the Company and GPB in connection with the issuance of the original senior secured convertible note. Additionally, the Company further agreed to amend the warrant issued with the original senior secured convertible note, to adjust the number of shares issuable upon exercise of the warrant to equal the number of shares that will initially be issuable upon conversion of the new convertible note (without giving effect to any beneficial ownership limitations set forth in the terms of the new convertible note). As an inducement to GPB to enter into these transactions, the Company agreed to increase the royalty payable to GPB pursuant to its consulting agreement with us on December 7, 2016 from 3.5% to 3.85% of revenues from the sales of the Company's products.

On August 7, 2017, the Company entered into a forbearance agreement with GPB, with regard to the senior secured convertible note. Under the forbearance agreement, GPB has agreed to forbear from exercising certain of its rights and remedies (but not waive such rights and remedies), arising as a result of the Company's failure to pay the monthly interest due and owing on the note. In consideration for the forbearance, the Company agreed to waive, release, and discharge GPB from all claims against GPB based on facts existing on or before the date of the forbearance agreement in connection with the note, or the dealings between the Company and GPB, or the Company's equity holders and GPB, in connection with the note. Pursuant to the forbearance agreement, the Company has reaffirmed its obligations under the note and related documents and executed a confession of judgment regarding the amount due under the note, which GPB may file upon any future event of default by the Company. During the forbearance period, the Company must continue to comply will all the terms, covenants, and provisions of the note and related documents.

The "Forbearance Period" shall mean the period beginning on the date hereof and ending on the earliest to occur of: (i) the date on which Lender delivers to Company a written notice terminating the Forbearance Period, which notice may be delivered at any time upon or after the occurrence of any Forbearance Default (as hereinafter defined), and (ii) the date Company repudiates or asserts any defense to any Obligation or other liability under or in respect of this Agreement or the Transaction Documents or applicable law, or makes or pursues any claim or cause of action against Lender; (the occurrence of any of the foregoing clauses (i) and (ii), a "Termination Event"). As used herein, the term "Forbearance Default" shall mean: (A) the occurrence of any Default or Event of Default other than the Specified Default; (B) the failure of Company to timely comply with any material term, condition, or covenant set forth in this Agreement; (C) the failure of any representation or warranty made by Company under or in connection with this Agreement to be true and complete in all material respects as of the date when made; or (D) Lender's reasonable belief that Company: (1) has ceased or is not actively pursuing mutually acceptable restructuring or foreclosure alternatives with Lender; or (2) is not negotiating such alternatives in good faith. Any Forbearance Default will not be effective until one (1) Business Day after receipt by Company of written notice from Lender of such Forbearance Default. Any effective Forbearance Default shall constitute an immediate Event of Default under the Transaction Documents.

The total amount attributed to convertible debt in default is \$2,354,000 and \$2,321,000, for the periods ended September 30, 2018 and December 31, 2017.

On September 4, 2018, the Company entered into an exchange agreement and promissory note with Dr. Faupel. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Faupel. In the exchange agreement Dr. Faupel, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$660,895 for \$207,111 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Faupel will receive 75,000 stock options, with 25,000 vesting immediately and the remaining vesting monthly over three years. Dr. Faupel will also receive 448,374 options at \$.25 or market price, whichever is less; contingent on shareholder vote and board approval. If the options are not granted, the Company shall owe Dr. Faupel \$113,000. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$199,079 and a capital contribution of \$234,990.

On September 4, 2018, the Company entered into an exchange agreement and promissory note with Dr. Cartwright. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Cartwright. In the exchange agreement Dr. Cartwright, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$1,621,499 for \$319,204 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Cartwright will receive 100,000 stock options, with 25,000 vesting immediately and the remaining vesting monthly over three years. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$840,391 and a capital contribution of \$431,519.

## **11. INCOME (LOSS) PER COMMON SHARE**

Basic net income (loss) per share attributable to common stockholders amounts are computed by dividing the net income (loss) plus preferred stock dividends and deemed dividends on preferred stock by the weighted average number of shares outstanding during the year.

Diluted net income (loss) per share attributable to common stockholders amounts are computed by dividing the net income (loss) plus preferred stock dividends, deemed dividends on preferred stock, after-tax interest on convertible debt and convertible dividends by the weighted average number of shares outstanding during the year, plus Series C convertible preferred stock, convertible debt, convertible preferred dividends and warrants convertible into common stock shares.

The following table sets forth pertinent data relating to the computation of basic and diluted net loss per share attributable to common shareholders.

In thousands	Nine months ended	
	September 30, 2018	2017
Net Income (loss)	\$3,650	\$(3,761)
Basic weighted average number of shares outstanding	201,231	2,632
Net income (loss) per share (basic)	\$0.018	\$(1.43 )
Diluted weighted average number of shares outstanding	10,988,645	—
Net income per share (diluted)	0.0003	—
Dilutive equity instruments (number of equivalent units):		
Stock options	—	—
Preferred stock	1,089,412	—
Convertible debt	6,648,318	—
Warrants	3,049,685	—
Total Dilutive instruments	10,988,645	—

## 12. SUBSEQUENT EVENTS

On October 19, 2018, the Company held its 2018 Annual Meeting of Stockholders (the “Annual Meeting”). As described in the Company’s Definitive Proxy Statement on Schedule 14A, as amended, originally filed with the Securities and Exchange Commission on October 11, 2018, at the Annual Meeting, stockholders of the Company voted and approved the following proposals: (1) the election of the director-nominees (the “Directors”) of the Company’s board of directors (the “Board”), with the five Directors receiving the highest number of affirmative votes cast by holders of shares of the Company’s common stock and holders of the Company’s Series C2 Preferred Stock, voting as a single class; (2) the ratification of the appointment of UHY LLP as the Company’s independent registered public accounting firm by a majority of the votes cast by the holders of common stock and of Series C2 Preferred Stock, voting as a single class; (3) an amendment to the Restated Certificate of Incorporation, as amended (the “Certificate of Incorporation”), to enable a potential reverse split of the issued and outstanding shares of common stock at a ratio of between 1-for-25 and 1-for-800, with such ratio to be determined at the sole discretion of the Board and with such reverse split to be effected at such time and date on or before March 31, 2019, if at all, as determined by the Board in its sole discretion (the “Reverse Split Amendment”) by a majority of the issued and outstanding common stock and Series C2 Preferred Stock voting as a single class; (4) the adoption of an amendment to the Certificate of Incorporation, to, among other things, increase the Company’s authorized common stock from 1,000,000,000 shares to 3,000,000,000 shares; and (5) the adoption of the Company’s 2018 Stock Option Plan and the material terms thereunder (the “Plan”) by a majority of the votes cast by the holders of common stock and of Series C2 Preferred Stock, voting as a single class.

On November 7, 2018, the Company increased the number of common stock shares authorized from one billion to three billion.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements in this report which express "belief," "anticipation" or "expectation," as well as other statements which are not historical facts, are forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those that may be set forth under "Risk Factors" below and elsewhere in this report, as well as in our annual report on Form 10-K for the year ended December 31, 2017 and subsequently filed quarterly reports on Form 10-Q. Examples of these uncertainties and risks include, but are not limited to:

- access to sufficient debt or equity capital to meet our operating and financial needs;
- the extent of dilution of the holdings of our existing stockholders upon the issuance, conversion or exercise of securities issued as part of our capital raising efforts;
- the effectiveness and ultimate market acceptance of our products and our ability to generate sufficient sales revenues to sustain our growth and strategy plans;
- whether our products in development will prove safe, feasible and effective;
- whether and when we or any potential strategic partners will obtain required regulatory approvals in the markets in which we plan to operate;
- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;
- the lack of immediate alternate sources of supply for some critical components of our products;
- our ability to establish and protect the proprietary information on which we base our products, including our patent and intellectual property position;
- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines;
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products; and
- other risks and uncertainties described from time to time in our reports filed with the SEC.

The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this report.

### OVERVIEW

We are a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. Our primary focus is the sales and marketing of our LuViva® Advanced Cervical Scan non-invasive cervical cancer detection device. The underlying technology of LuViva primarily relates to the use of biophotonics for the non-invasive detection of cancers. LuViva is designed to identify cervical cancers and precancers

painlessly, non-invasively and at the point of care by scanning the cervix with light, then analyzing the reflected and fluorescent light.

LuViva provides a less invasive and painless alternative to conventional tests for cervical cancer screening and detection. Additionally, LuViva improves patient well-being not only because it eliminates pain, but also because it is convenient to use and provides rapid results at the point of care. We focus on two primary applications for LuViva: first, as a cancer screening tool in the developing world, where infrastructure to support traditional cancer-screening methods is limited or non-existent, and second, as a triage following traditional screening in the developed world, where a high number of false positive results cause a high rate of unnecessary and ultimately costly follow-up tests.

We are a Delaware corporation, originally incorporated in 1992 under the name “SpectRx, Inc.,” and, on February 22, 2008, changed our name to Guided Therapeutics, Inc. At the same time, we renamed our wholly owned subsidiary, InterScan, which originally had been incorporated as “Guided Therapeutics.”

Since our inception, we have raised capital through the public and private sale of debt and equity, funding from collaborative arrangements, and grants.



Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced net losses since our inception and, as of September 30, 2018 we had an accumulated deficit of approximately \$134.9 million. To date, we have engaged primarily in research and development efforts and the early stages of marketing our products. We do not have significant experience in manufacturing, marketing or selling our products. We may not be successful in growing sales for our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products requires substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue through at least the end of 2018 as we continue to expend substantial resources to complete commercialization of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance capabilities, and conduct further research and development.

Our product revenues to date have been limited. In 2017, the majority of our revenues were from the sale of LuViva devices and disposables. We expect that the majority of our revenue in 2018 will be derived from revenue from the sale of LuViva devices and disposables.

## **RECENT DEVELOPMENTS**

On August 31, 2018, we entered into agreements with certain holders of the our Series C1 preferred stock, par value \$0.001 per share (the “Series C1 Preferred Stock”), including John Imhoff, the chairman of our board of directors, and Mark Faupel, the Chief Operating Officer and a director of our company (the “Exchange Agreements”), pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of our newly created Series C2 preferred stock, par value \$0.001 per share (the “Series C2 Preferred Stock”). In total, for 3,262.25 shares of Series C1 Preferred Stock to be surrendered, we issued 3,262.25 shares of Series C2 Preferred Stock.

On October 19, 2018, we held our 2018 Annual Meeting of Stockholders (the “Annual Meeting”). As described in the our Definitive Proxy Statement on Schedule 14A, as amended, originally filed with the Securities and Exchange Commission on October 11, 2018, at the Annual Meeting, stockholders of our company voted and approved the following proposals: (1) the election of the director-nominees (the “Directors”) of our board of directors (the “Board”), with the five Directors receiving the highest number of affirmative votes cast by holders of shares of our common stock, par value \$0.001 per share (the “Common Stock”) and holders of the our Series C2 Preferred Stock, par value \$0.001 per share (the “Preferred Stock”), voting as a single class; (2) the ratification of the appointment of UHY LLP as our independent registered public accounting firm by a majority of the votes cast by the holders of Common Stock and of Preferred Stock, voting as a single class; (3) an amendment to the Restated Certificate of Incorporation, as amended (the “Certificate of Incorporation”), to enable a potential reverse split of the issued and outstanding shares of Common Stock at a ratio of between 1-for-25 and 1-for-800, with such ratio to be determined at the sole discretion of the Board and with such reverse split to be effected at such time and date on or before March 31, 2019, if at all, as determined by the Board in its sole discretion by a majority of the issued and outstanding Common Stock and Preferred Stock voting

as a single class; (4) the adoption of an amendment to the Certificate of Incorporation, to, among other things, increase our authorized Common Stock from 1,000,000,000 shares to 3,000,000,000 shares; and (5) the adoption of our 2018 Stock Option Plan and the material terms thereunder by a majority of the votes cast by the holders of Common Stock and of Preferred Stock, voting as a single class.

## **CRITICAL ACCOUNTING POLICIES**

Our material accounting policies, which we believe are the most critical to investors understanding of our financial results and condition, are discussed below. Because we are still early in our enterprise development, the number of these policies requiring explanation is limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

**Revenue Recognition:** We recognize revenue from contracts on a straight-line basis, over the terms of the contract. We recognize revenue from grants based on the grant agreement, at the time the expenses are incurred. Revenue from the sale of the Company's products is recognized upon shipment of such products to its distributors.

**Valuation of Deferred Taxes:** We account for income taxes in accordance with the liability method. Under the liability method, we recognize deferred assets and liabilities based upon anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. We establish a valuation allowance to the extent that it is more likely than not that deferred tax assets will not be utilized against future taxable income.

**Valuation of Equity Instruments Granted to Employee, Service Providers and Investors:** On the date of issuance, the instruments are recorded at their fair value as determined using either the Black-Scholes valuation model or Monte Carlo Simulation model. See Note 3 to the consolidated financial statements accompanying this report for the assumptions used in the Black-Scholes valuation.

**Allowance for Accounts Receivable:** We estimate losses from the inability of our distributors to make required payments and periodically review the payment history of each of our distributors, as well as their financial condition, and revise our reserves as a result.

**Inventory Valuation:** All inventories are stated at lower of cost or net realizable value, with cost determined substantially on a “first-in, first-out” basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when purchased.

## **RESULTS OF OPERATIONS**

### **COMPARISON OF THE THREE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017**

*Sales Revenue, Cost of Sales and Gross Loss from Devices and Disposables:* Revenues from the sale of LuViva devices and disposables for the three months ended September 30, 2018 and 2017 were \$2,000 and 33,000, respectively. Revenues decreased by approximately \$31,000, or 94% from the same period in 2017. The decrease was due to less activity in sales orders being shipped in 2018 and lack of funding to support sales and marketing efforts. Related costs of sales were approximately nil and approximately \$97,000 for the three months ended September 30, 2018 and 2017, respectively. Costs of sales for the three months ended September 30, 2018 were approximately \$97,000, or 100% lower than the same period in 2017. This resulted in a gross profit of approximately \$2,000 on the sales of devices and disposables for the three months ended September 30, 2018, compared with a gross loss of approximately \$64,000 for the same period in 2017.

*Research and Development Expenses:* Research and development expenses for the three months ended September 30, 2018 decreased to approximately \$43,000, from approximately \$69,000 for the same period in 2017. The decrease, of approximately \$26,000, or 37%, was primarily due to decreases in payroll expenses.

*Sales and Marketing Expenses:* Sales and marketing expenses for the three months ended September 30, 2018 increased to approximately \$39,000, from approximately \$37,000 for the same period in 2017. The increase, of approximately \$2,000, or 5% was not materially different.

*General and Administrative Expenses:* General and administrative expenses for the three months ended September 30, 2018 decreased to approximately \$154,000, from approximately \$1,169,000 for the same period in 2017. The

decrease, of approximately \$1,015,000, or 87%, was primarily related to other professional fee expenses and bad debt expenses incurred during the prior period and payments required for financing agreements.

*Other Income:* Other income for the three months ended September 30, 2018 decreased to approximately \$2,000, compared to \$3,000 for the same period in 2017. The decrease of approximately \$1,000, or 33%, was primarily related to a refund for utility deposits.

*Interest Expense:* Interest expense for the three months ended September 30, 2018 decreased to approximately \$239,000, compared to \$268,000 for the same period in 2017. The decrease of approximately \$29,000, or 11%, was primarily due to less debt issuance costs than those incurred during the same period.

*Fair Value of Warrants Expense:* Fair value of warrants recovery for the three months ended September 30, 2018 increased to approximately \$1,314,000, compared to an expense of \$761,000 for the same period in 2017. The increase of approximately \$553,000, or 73%, was primarily due to the significant changes in warrant conversion prices.

*Gain from extinguishment of debt:* Gain from the restructuring and exchange of debt due to officers for the three months ended September 30, 2018 increased to approximately \$1,039,000, compared to nil for the same period in 2017.

*Net Income (loss):* Net loss attributable to common stockholders was approximately \$757,000, or \$0.002 per share, for the three months ended September 30, 2018, compared to a net loss of \$2,417,000, or \$0.35 per share, for the same period in 2017. The increase of \$1,663,000, or 69%, was for reasons outlined above.

## COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

*Sales Revenue, Cost of Sales and Gross Loss from Devices and Disposables:* Revenues from the sale of LuViva devices and disposables for the nine months ended September 30, 2018 and 2017 were \$15,000 and \$137,000, respectively. Revenues decreased by approximately \$122,000, or 89% from the same period in 2017. The decrease was due to less activity in sales orders being shipped in 2018 and lack of funding to support sales and marketing efforts. Related costs of sales were approximately \$3,000 and \$195,000 for the nine months ended September 30, 2018 and 2017, respectively. Costs of sales for the nine months ended September 30, 2018 were approximately \$192,000, or 98% lower than the same period in 2017. This resulted in a gross profit of approximately \$12,000 on the sales of devices and disposables for the nine months ended September 30, 2018, compared with a gross loss of approximately \$58,000 for the same period in 2017.

*Research and Development Expenses:* Research and development expenses for the nine months ended September 30, 2018 decreased to approximately \$175,000, from approximately \$251,000 for the same period in 2017. The decrease, of approximately \$76,000, or 30%, was primarily due to decreases in payroll expenses.

*Sales and Marketing Expenses:* Sales and marketing expenses for the nine months ended September 30, 2018 decreased to approximately 156,000, from approximately \$187,000 for the same period in 2017. The decrease, of approximately \$31,000, or 17%, was primarily due to Company-wide expense reduction and cost savings efforts.

*General and Administrative Expenses:* General and administrative expenses for the nine months ended September 30, 2018 decreased to approximately \$780,000, from approximately \$1,894,000 for the same period in 2017. The decrease, of approximately \$1,114,000, or 59%, was primarily related to lower compensation and option expenses incurred during the same period.

*Other Income:* Other income for the nine months ended September 30, 2018 increased to approximately \$41,000, compared to \$18,000 for the same period in 2017. The increase of approximately \$23,000, or 128%, was primarily related to a refund from a commercial insurance policy.

*Interest Expense:* Interest expense for the nine months ended September 30, 2018 decreased to approximately \$795,000, compared to \$814,000 for the same period in 2017. The decrease of approximately \$19,000, or 2%, was primarily due to less debt issuance costs than those incurred during the same period.

*Fair Value of Warrants Expense:* Fair value of warrants recovery for the nine months ended September 30, 2018 increased to approximately \$4,572,000, compared to \$359,000 for the same period in 2017. The increase of approximately \$4,931,000, or 1,374%, was primarily due to the significant changes in warrant conversion prices.

*Gain from extinguishment of debt:* Gain from the restructuring and exchange of debt due to officers for the nine months ended September 30, 2018 increased to approximately \$1,039,000, compared to nil for the same period in 2017.

*Net Income (loss):* Net Income attributable to common stockholders was approximately \$3,650,000, or \$0.018 per share, for the nine months ended September 30, 2018, compared to a net loss of \$3,761,000, or \$1.43 per share, for the same period in 2017. The increase of \$7,411,000, or 197%, was for reasons outlined above.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since our inception, we have raised capital through the public and private sale of debt and equity, funding from collaborative arrangements, and grants. At September 30, 2018, we had cash of approximately \$70,000 and a negative working capital of approximately \$10.2 million.

Our major cash flows for the nine months ended September 30, 2018 consisted of cash out-flows of \$1,054,000 from operations, including approximately \$3,758,000 of net income, (\$4,572,000 from a gain for the change in the fair value of warrants and \$1,039,000 from a gain for the extinguishment of debt), and a net change from financing activities of \$1,123,000, which primarily represented the proceeds received from debt financing.

Our cash flows from convertible debt is described in more detail in NOTE 9 – SHORT-TERM CONVERTIBLE DEBT.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements, as soon as possible. We cannot be certain that our existing and available capital resources will be sufficient to satisfy our funding requirements through 2018. We are evaluating various options to further reduce our cash requirements to operate at a reduced rate, as well as options to raise additional funds, including loans.

Generally, substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required U.S. and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure to obtain capital would have a material adverse effect on our business, financial condition and results of operations. Based on discussions with our distributors, we expect to generate purchase orders for approximately \$2 million in LuViva devices and disposables in 2018, and expect those purchase orders to result in actual sales of between \$0.1 million and \$0.5 million in 2018, representing what we view as current demand for our products. We cannot be assured that we will generate all or any of these additional purchase orders, or that existing orders will not be canceled by the distributors or that parts to build product will be available to meet demand, such that existing orders will result in actual sales. Because we have a short history of sales of our products, we cannot confidently predict future sales of our products beyond this time frame and cannot be assured of any particular amount of sales. Accordingly, we have not identified any particular trends with regard to sales of our products.

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. The above factors raise substantial doubt about our ability to continue as a going concern, as more fully discussed in Note 1 to the consolidated financial statements contained herein and in the report of our independent registered public accounting firm accompanying our financial statements contained in our annual report on Form 10-K for the year ended December 31, 2017.

#### **Off-Balance Sheet Arrangements**

We have no material off-balance sheet arrangements, no special purpose entities, and no activities that include non-exchange-traded contracts accounted for at fair value.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Disclosure Controls and Procedures**

The Company under the supervision and with the participation of management, including the Chief Executive Officer (principal executive officer) and the Chief Financial Officer (principal financial officer), evaluated the effectiveness of our “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”)) as of September 30, 2018. The controls and system currently used by the Company to calculate and record inventory is not operating effectively. Additionally, the Company lacks the resources to properly research and account for complex transactions. The combination of these controls deficiencies has resulted in a material weakness in our internal control over financial reporting.

Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) were not effective as of September 30, 2018 to provide reasonable assurance that (1) information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and (2) information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

The effectiveness of any system of controls and procedures is subject to certain limitations, and, as a result, there can be no assurance that our controls and procedures will detect all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be attained.

#### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**



**ITEM 1. LEGAL PROCEEDINGS**

From time to time, the Company may be involved in various legal proceedings and claims arising in the ordinary course of business. Management believes that the disposition of these matters, individually or in the aggregate, is not expected to have a material adverse effect on the Company's financial condition. See Note 6 to the financial statements.

**ITEM 1A. RISK FACTORS**

Please refer to Part I, Item 1A, "Risk Factors," in our annual report on Form 10-K for the year ended December 31, 2017, for information regarding factors that could affect our results of operations, financial condition and liquidity.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. EXHIBITS**

<u>Exhibit Number</u>	<u>Exhibit Description</u>
31*	Rule 13a-14(a)/15d-14(a) Certification
32*	Section 1350 Certification
101.1* XBRL	

*\*Filed herewith*

**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**GUIDED THERAPEUTICS, INC.**

/s/ Gene S. Cartwright

By: Gene S. Cartwright  
President, Chief Executive Officer and  
Acting Chief Financial Officer

Date: November 14, 2018