

**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

For the quarterly period ended March 31, 2019

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-35814

**Harrow Health, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**45-0567010**

(I.R.S. Employer  
Identification No.)

**12264 El Camino Real, Suite 350  
San Diego, CA**

(Address of principal executive offices)

**92130**

(Zip code)

**(858) 704-4040**

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a small reporting company, or an emerging growth company.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

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

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

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

Title of each class	Trading Symbol(s)	Name on exchange on which registered
Common Stock, \$0.001 par value per share	HROW	The NASDAQ Capital Market

As of May 8, 2019, 24,718,649 shares of the registrant's common stock, \$0.001 par value, were outstanding.

HARROW HEALTH, INC.

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**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**HARROW HEALTH, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In thousands, except share data)**

	March 31, 2019 <u>(unaudited)</u>	December 31, 2018
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents, including restricted cash of \$200	\$ 4,265	\$ 6,838
Investment in Eton Pharmaceuticals	28,000	21,420
Accounts receivable, net	2,194	1,914
Inventories	2,388	1,834
Prepaid expenses and other current assets	1,658	837
Total current assets	<u>38,505</u>	<u>32,843</u>
Property, plant and equipment, net	6,242	6,375
Operating lease right-of-use assets	6,195	-
Intangible assets, net	3,112	3,059
Investment in Surface Pharmaceuticals	4,704	4,947
Investment in Melt Pharmaceuticals	5,525	-
Goodwill	2,227	2,227
<b>TOTAL ASSETS</b>	<u><u>\$ 66,510</u></u>	<u><u>\$ 49,451</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 6,143	\$ 6,250
Accrued payroll and related liabilities	1,092	2,283
Deferred revenue and customer deposits	359	119
Current portion of note payable, net of unamortized debt discount	2,552	2,529
Current portion of operating lease obligations	511	-
Current portion of finance lease obligations, net of unamortized discount	553	720
Total current liabilities	<u>11,210</u>	<u>11,901</u>
Operating lease obligations, net of current portion	6,083	-
Finance lease obligations, net of current portion and unamortized discount	32	-
Accrued expenses, net of current portion	800	800
Note payable, net of current portion and unamortized debt discount	11,351	11,999
<b>TOTAL LIABILITIES</b>	<u>29,476</u>	<u>24,700</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 24,718,649 and 24,339,610 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	25	24
Additional paid-in capital	99,887	98,938
Accumulated deficit	(62,853)	(74,211)
<b>TOTAL HARROW HEALTH, INC. STOCKHOLDERS' EQUITY</b>	<u>37,059</u>	<u>24,751</u>
Noncontrolling interests	(25)	-
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u>37,034</u>	<u>24,751</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u><u>\$ 66,510</u></u>	<u><u>\$ 49,451</u></u>

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

**HARROW HEALTH, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except for share and per share data)

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
<b>Revenues:</b>		
Sales, net	\$ 12,283	\$ 8,855
License revenues	7	10
Total revenues	12,290	8,865
Cost of sales	(3,898)	(4,071)
Gross profit	8,392	4,794
<b>Operating expenses:</b>		
Selling, general and administrative	8,543	6,488
Research and development	405	87
Total operating expenses	8,948	6,575
Loss from operations	(556)	(1,781)
<b>Other income (expense):</b>		
Interest expense, net	(603)	(663)
Investment gain from and equity in net loss of Melt Pharmaceuticals, net	5,525	-
Equity in net loss of Surface Pharmaceuticals	(243)	-
Investment gain from (equity in net loss of) Eton Pharmaceuticals	6,580	(1,069)
Other income, net	630	-
Total other income (expense), net	11,889	(1,732)
Total net income (loss) including noncontrolling interests	11,333	(3,513)
Net loss attributable to noncontrolling interests	25	-
Net income (loss) attributable to Harrow Health, Inc.	\$ 11,358	\$ (3,513)
Basic net income (loss) per share of common stock	\$ 0.46	\$ (0.17)
Diluted net income (loss) per share of common stock	\$ 0.43	\$ (0.17)
Weighted average number of shares of common stock outstanding, basic	24,841,386	20,949,199
Weighted average number of shares of common stock outstanding, diluted	26,589,695	20,949,199

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

**HARROW HEALTH, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For the periods ended March 31, 2019 and 2018**  
(In thousands, except for share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
Balance at December 31, 2017	20,623,129	\$ 21	\$ 91,430	\$ (88,836)	\$ 2,615	\$ -	\$ 2,615
Issuance of common stock in connection with:							
Vesting of RSUs, net of tax withholding	60,000	-	-	-	-	-	-
Sale of stock, net of costs (ATM)	69,376	-	122	-	122	-	122
Stock-based payment for services provided	60,700	-	108	-	108	-	108
Stock-based compensation expense	-	-	751	-	751	-	751
Net loss	-	-	-	(3,513)	(3,513)	-	(3,513)
Balance at March 31, 2018	<u>20,813,205</u>	<u>\$ 21</u>	<u>\$ 92,411</u>	<u>\$ (92,349)</u>	<u>\$ 83</u>	<u>\$ -</u>	<u>\$ 83</u>
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
Balance at December 31, 2018	24,339,610	\$ 24	\$ 98,938	\$ (74,211)	\$ 24,751	\$ -	\$ 24,751
Issuance of common stock in connection with:							
Exercise of warrants	364,039	1	161	-	162	-	162
Stock-based payment for services provided	15,000	-	75	-	75	-	75
Stock-based compensation expense	-	-	713	-	713	-	713
Net income	-	-	-	11,358	11,358	(25)	11,333
Balance at March 31, 2019	<u>24,718,649</u>	<u>\$ 25</u>	<u>\$ 99,887</u>	<u>\$ (62,853)</u>	<u>\$ 37,059</u>	<u>\$ (25)</u>	<u>\$ 37,034</u>

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

**HARROW HEALTH, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income (loss) (including noncontrolling interests)	\$ 11,333	\$ (3,513)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization of property, plant and equipment	390	399
Amortization of intangible assets	62	60
Amortization of operating lease right-of-use assets	130	-
Amortization of debt issuance costs and discount	135	159
Investment (gain) from and equity in net loss of Eton Pharmaceuticals	(6,580)	1,069
Investment (gain) from and equity in net loss of Melt Pharmaceuticals, net	(5,525)	-
Equity in net loss of Surface Pharmaceuticals	243	-
Gain on sale and disposal of assets	(4)	-
Stock-based payment of consulting services	75	-
Stock-based compensation	713	751
Changes in assets and liabilities:		
Accounts receivable	(280)	55
Inventories	(554)	209
Prepaid expenses and other current assets	(821)	(137)
Accounts payable, accrued expenses and other liabilities	158	106
Accrued payroll and related liabilities	(1,191)	(167)
Deferred revenue and customer deposits	240	44
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(1,476)</b>	<b>(965)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Repayment of note receivable	-	4
Proceeds on sale and disposal of assets	4	-
Investment in patent and trademark assets	(115)	(76)
Purchases of property, plant and equipment	(213)	(192)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(324)</b>	<b>(264)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Payments on finance lease obligations	(185)	(167)
Payments on Park deferred acquisition obligation	-	(53)
Principal payments on note payable	(750)	-
Net proceeds from ATM sales of common stock	-	122
Net proceeds from exercise of warrants	162	-
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(773)</b>	<b>(98)</b>
<b>NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(2,573)</b>	<b>(1,327)</b>
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	6,838	4,219
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period</b>	<b>\$ 4,265</b>	<b>\$ 2,892</b>
<b>RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>		
Cash and cash equivalents	\$ 4,065	\$ 2,692
Restricted cash	200	200
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD</b>	<b>\$ 4,265</b>	<b>\$ 2,892</b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid for income taxes	\$ -	\$ 2
Cash paid for interest	\$ 467	\$ 483
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Issuance of common stock for consulting services, included in accounts payable and accrued expenses	\$ -	\$ 108
Changes in accrued property and equipment purchases	\$ 5	\$ -
Acquisition of property, plant and equipment with finance lease obligations	\$ 40	\$ -

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

**HARROW HEALTH, INC.**  
**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**For the three months ended March 31, 2019 and 2018**  
**(Dollar amounts in thousands, except share and per share data)**

**NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION**

**Company and Background**

Harrow Health, Inc. (together with its subsidiaries, unless the context indicates or otherwise requires, the “Company” or “Harrow”) specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. Prior to 2017, the Company’s business was primarily focused on its ImprimisRx business, the nation’s leading ophthalmology pharmaceutical compounding business, and Park Compounding, Inc. (“Park”), a leading health and wellness compounding business. Since 2017, in addition to wholly-owning ImprimisRx and Park, the Company also has equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”). In 2018, the Company also founded its subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”) and Radley Pharmaceuticals, Inc. (“Radley”). In February 2019, the Company entered into an agreement with Elle Pharmaceutical, Inc. (“Elle”) in which Mayfield issued 1,000,000 shares of its common stock to Elle (see Note 14). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Surface, Melt, Radley and Mayfield.

**Basis of Presentation**

Harrow has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for audited financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 or for any other period. For further information, refer to the Company’s audited consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018.

The consolidated financial statements include the accounts of Harrow and its wholly owned subsidiaries, as well as Mayfield, a 72% majority owned subsidiary of Harrow. The remaining 28% of Mayfield is owned by Elle. Mayfield was organized to develop women’s health focused drug candidates. All inter-company accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which we have a controlling financial interest. We consolidate subsidiaries in which we hold, directly or indirectly, more than 50% of the voting rights.

The condensed consolidated balance sheets at March 31, 2019 and December 31, 2018 and the condensed consolidated statements of operations and cash flows for the period ended March 31, 2019 include our accounts and those of our wholly owned subsidiaries as well as Mayfield. The condensed consolidated statements of operations and cash flows for the period ended March 31, 2018 include our accounts and those of our wholly owned subsidiaries.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The following represents an update for the three months ended March 31, 2019 to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018.

**Liquidity**

The Company has incurred significant operating losses and negative cash flows from operations since its inception. The Company incurred operating losses of \$556 and \$1,781 for the three months ended March 31, 2019 and 2018, respectively, and had an accumulated deficit of \$62,853 and \$74,211 as of March 31, 2019 and December 31, 2018, respectively. In addition, the Company used cash in operating activities of \$1,476 and \$965 for the three months ended March 31, 2019 and 2018, respectively.

While there is no assurance, the Company believes its existing cash resources and restricted cash of \$4,265 at March 31, 2019, will be sufficient to sustain the Company's planned level of operations for at least the next twelve months. However, estimates of operating expenses and working capital requirements could be incorrect, and the Company could use its cash resources faster than anticipated. Further, some or all of the ongoing or planned activities may not be successful and could result in further losses.

The Company may seek to increase liquidity and capital resources by one or more of the following which may include, but are not limited to: the sale of assets and/or businesses, obtaining financing through the issuance of equity, debt, or convertible securities; and working to increase revenue growth through sales. There is no guarantee that the Company will be able to obtain capital when needed on terms it deems as acceptable, or at all.

### **Segments**

The Company's chief operating decision-maker is its Chief Executive Officer who makes resource allocation decisions and assesses performance based on financial information presented on as operating segments. The Company has identified two operating segments as reportable segments. See Note 15 for more information regarding the Company's reportable segments.

### **Noncontrolling Interests**

The Company recognizes any noncontrolling interest as a separate line item in equity in the condensed consolidated financial statements. A noncontrolling interest represents the portion of equity ownership in a less-than-wholly owned subsidiary not attributable to the Company. Generally, any interest that holds less than 50% of the outstanding voting shares is deemed to be a noncontrolling interest; however, there are other factors, such as decision-making rights, that are considered as well. The Company includes the amount of net income (loss) attributable to noncontrolling interests in consolidated net income (loss) on the face of the condensed consolidated statements of operations.

The Company provides in the condensed consolidated statements of stockholders' equity a reconciliation at the beginning and the end of the period of the carrying amount of total equity, equity attributable to the parent, and equity attributable to the noncontrolling interest that separately discloses:

- (1) Net income or loss;
- (2) transactions with owners acting in their capacity as owners, showing separately contributions from and distributions to owners; and
- (3) each component of other income or loss.

### **Basic and Diluted Net Income (Loss) per Common Share**

Basic net income (loss) per common share is computed by dividing income (loss) attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted income (loss) per share is computed by dividing the income (loss) attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period.

Basic and diluted net income (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period. Common stock equivalents (using the treasury stock or "if converted" method) from deferred acquisition obligations, convertible note payable, stock options, unvested restricted stock units ("RSUs") and warrants were 5,838,230 and 10,106,391 at March 31, 2019 and 2018, respectively, and, except for the three months ended March 31, 2019, are excluded from the calculation of diluted net (loss) per share for the periods presented, because the effect is anti-dilutive. Included in the basic and diluted net income (loss) per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at March 31, 2019 and 2018 was 270,783 and 152,790, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the three March 31, 2019 and 2018:

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Numerator – net income (loss) attributable to Harrow Health, Inc.	\$ 11,358	\$ (3,513)
Denominator – weighted average number of shares outstanding, basic	24,841,386	20,949,199
<b>Net income (loss) per share, basic</b>	<b>\$ 0.46</b>	<b>\$ (0.17)</b>

For three months ended March 31, 2019, the Company had net income. As a result, the Company computed diluted net income per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding during those periods. Diluted common equivalent shares for the three months ended March 31, 2019, consisted of the following:

	March 31, 2019
Diluted shares related to:	
Warrants	1,067,808
Stock options	680,501
Dilutive common equivalent shares	1,748,309

The following table shows the computation of diluted net income (loss) per share of common stock for the three months ended March 31, 2019 and 2018:

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Numerator – net income (loss) attributable to Harrow Health, Inc.	\$ 11,358	\$ (3,513)
Denominator – weighted average number of shares outstanding, basic	24,841,386	20,949,199
Dilutive common equivalent shares	1,748,309	-
Number of shares used for diluted earnings per share computation	26,589,695	20,949,199
<b>Net income (loss) per share, diluted</b>	<b>\$ 0.43</b>	<b>\$ (0.17)</b>

#### Investment in Eton Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 shares of Eton common stock, which represents approximately 19.86% of the equity and voting interests of Eton as of March 31, 2019. At March 31, 2019, the fair market value of Eton’s common stock was \$8.00 per share, the closing share price of Eton common stock on March 29, 2019, the last trading day of the period ended March 31, 2019. In accordance with the Accounting Standards Update (“ASU”) 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, for the three months ended March 31, 2019, the Company recorded an investment gain from its Eton common stock position of \$6,580, related to the change in fair market value of the Company’s investment in Eton during the measurement period. As of March 31, 2019, the fair market value of the Company’s investment in Eton was \$28,000.

In November 2018, the Company entered into a lock-up agreement, that prohibits the sale of any of its Eton common stock until November 2019, without the approval of National Securities Corporation.

Mark Baum, the Company’s Chief Executive Officer, is a member of the board of directors of Eton.

### **Investment in Melt Pharmaceuticals, Inc. – Related Party**

In April 2018, the Company formed Melt as a wholly owned subsidiary. In January and March of 2019, Melt entered into definitive stock purchase agreements (the “Melt Series A Preferred Stock Agreement”) with certain investors and closed on the purchase and sale of Melt’s Series A Preferred Stock (the “Melt Series A Stock”), totaling approximately \$11,400 of proceeds (collectively the “Melt Series A Round”) at a purchase price of \$5.00 per share. As a result, the Company lost voting and ownership control of Melt and ceased consolidating Melt’s financial statements. In connection with the Melt Series A Preferred Stock Agreement, Melt also entered into a Registration Rights Agreement and agreed to use commercially reasonable efforts to file, or confidentially submit, a registration statement on Form S-1 with the United States Securities and Exchange Commission by September 30, 2020 relating to an initial public offering of its common stock.

At the time of deconsolidation, the Company recorded a gain of \$5,810 and adjusted the carrying value in Melt to reflect the increased valuation of Melt and the Company’s new ownership interest in accordance with Accounting Standard Codification (“ASC”) 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares (which is approximately 44% of the equity interest as of March 31, 2019) of Melt and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Melt. Under this method, the Company recognizes earnings and losses of Melt in its consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company’s share of earnings and losses are based on the Company’s ownership interest of Melt. Any intra-entity profits and losses are eliminated. During the three months ended March 31, 2019, the Company recorded equity in net loss of Melt of \$285. As of March 31, 2019, the carrying value of the Company’s investment in Melt was \$5,525.

See Note 4 for more information and related party disclosure regarding Melt.

### **Investment in Surface Pharmaceuticals, Inc. – Related Party**

In April 2017, the Company formed Surface as a wholly owned subsidiary. In May and July 2018, Surface entered into and closed on a definitive stock purchase agreement with an institutional investor for the purchase of Surface’s Series A Preferred Stock (the “Surface Series A Stock”) that resulted in total proceeds to Surface of approximately \$21,000. At the time of the first closing in May 2018, the Company lost voting and ownership control of Surface and it ceased consolidating Surface’s financial statements. The Surface Series A Stock (i) was issued at a purchase price of \$3.30 per share; (ii) will vote together with the common stock and all other shares of stock of Surface having general voting power; (iii) will be entitled to the number of votes equal to the number of shares of preferred stock held; (iv) will hold liquidation preference over all other equity interests in Surface; and (v) will have mandatory conversion requirements into Surface common stock upon events including an underwritten initial public offering (“IPO”) of Surface common stock or similar transaction.

At the time of deconsolidation, the Company recorded a gain of \$5,320 and adjusted the carrying value in Surface to reflect the increased valuation of Surface and the Company’s new ownership interest in accordance with ASC 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interest as of March 31, 2019) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses of Surface in its consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company’s share of earnings and losses are based on the Company’s ownership interest of Surface. Any intra-entity profits and losses are eliminated. During the three months ended March 31, 2019, the Company recorded equity in net loss of Surface of \$243. As of March 31, 2019, the carrying value of the Company’s investment in Surface was \$4,704.

See Note 5 for more information and related party disclosure regarding Surface.

### Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued new lease accounting guidance in ASU No. 2016-02, *Leases* (Topic 842). This new guidance was initiated as a joint project with the International Accounting Standards Board to simplify lease accounting and improve the quality of and comparability of financial information for users. This new guidance would eliminate the concept of off-balance sheet treatment for “operating leases” for lessees for the vast majority of lease contracts. Under ASU No. 2016-02, at inception, a lessee must classify all leases with a term of over one year as either finance or operating, with both classifications resulting in the recognition of a defined “right-of-use” asset and a lease liability on the balance sheet. However, recognition in the income statement will differ depending on the lease classification, with finance leases recognizing the amortization of the right-of-use asset separate from the interest on the lease liability and operating leases recognizing a single total lease expense. Lessor accounting under ASU No. 2016-02 would be substantially unchanged from the previous lease requirements under GAAP. ASU No. 2016-02 took effect for public companies in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. On January 1, 2019, the Company adopted Topic 842 using the modified retrospective transition method with no impact to stockholders’ equity. As of March 31, 2019, the Company held on its condensed consolidated balance sheet \$6,195 for the right-of-use asset and \$6,594 for the related lease liability related to operating leases. The difference between the right of use asset and related lease liability is predominantly deferred rent and other related lease expenses under the new lease accounting standard. For additional information regarding how the Company is accounting for leases under Topic 842, refer to Note 12.

### Recently Issued Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other*. This guidance simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in the current two-step impairment test under ASC 350. The updated standard eliminates the requirement to calculate a goodwill impairment charge using Step 2. If a reporting unit’s carrying amount exceeds its fair value, an entity will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit. ASU 2017-04 is effective for reporting periods beginning after December 31, 2019 on a prospective basis, and early adoption is permitted. The Company does not expect ASU 2017-04 to have a material effect on the Company’s financial position, results of operations and cash flows.

### NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has two primary streams of revenues: (1) revenues recognized from our sale of products within our pharmacy services and (2) revenues recognized from intellectual property license and asset purchase agreements.

#### *Product Revenues from Pharmacy Services*

The Company sells prescription drugs directly through our pharmacy and outsourcing facility network. Revenues from our pharmacy services divisions includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core principle of ASC 606, we have identified the following:

1. Identify the contract(s) with a customer: A contract exists with a customer at the time the prescription or order is received by the Company.

2. Identify the performance obligations in the contract: The order received contains the performance obligations to be met, in almost all cases the product the customer is wishing to receive. If we are unable to be meet the performance obligation, the customer is notified.
3. Determine the transaction price: the transaction price is based on the product being sold to the customer, and any related customer discounts. These amounts are pre-determined and built into our order management software.
4. Allocate the transaction price to the performance obligations in the contract: The transaction price associated with the product(s) being ordered is allocated according to the pre-determined amounts.
5. Recognize revenue when (or as) the entity satisfies a performance obligation: At the time of shipment from the pharmacy or outsourcing facility, the performance obligation has been met.

The following revenue recognition policy has been established for the pharmacy services division:

Revenues generated from prescription or office use drugs sold by our pharmacies and outsourcing facility are recognized when the prescription is shipped. At the time of shipment, the pharmacy services division has performed substantially all of its obligations under its client contracts and does not experience a significant level of returns or reshipments. Determination of criteria (3) and (4) is based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. The Company records reductions to revenue for discounts at the time of the initial sale. Estimated returns and allowances and other adjustments are provided for in the same period during which the related sales are recorded and are based on actual returns history. The rate of returns is analyzed annually to determine historical returns experience. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. The Company will defer any revenues received for a product that has not been delivered or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered and no refund will be required.

#### *Intellectual Property License Revenues*

The Company currently holds five intellectual property license and related agreements in which the Company has promised to grant a license or sale which provides a customer with right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple element arrangements, each of which revenue is recognized at the point of time the performance obligation is met.

Non-refundable fees that are not contingent on any future performance by the Company and require no consequential continuing involvement on the part of the Company are recognized as revenue when the license term commences and the licensed data, technology, compounded drug preparation and/or other deliverable is delivered. Such deliverables may include physical quantities of compounded drug preparations, design of the compounded drug preparations and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patent applications for such compounded drug preparations. The Company defers recognition of non-refundable fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee and that are separate and independent of the Company's performance under the other elements of the arrangement. In addition, if the Company's continued involvement is required, through research and development services that are related to its proprietary know-how and expertise of the delivered technology or can only be performed by the Company, then such non-refundable fees are deferred and recognized over the period of continuing involvement. Guaranteed minimum annual royalties are recognized on a straight-line basis over the applicable term.

Revenue disaggregated by revenue source for the three months ended March 31, 2019 and 2018, consists of the following:

	For the Three months ended March 31,	
	2019	2018
<b>Product sales, net</b>	\$ 12,283	\$ 8,855
<b>License revenues</b>	7	10
<b>Total revenues</b>	<u>\$ 12,290</u>	<u>\$ 8,865</u>

Deferred revenue and customer deposits at March 31, 2019 and December 31, 2018, was \$359 and \$119, retrospectively. All deferred revenue and customer deposit amounts at December 31, 2018 were recognized as revenue during the three months ended March 31, 2019.

**NOTE 4. INVESTMENT IN MELT PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS**

In December 2018, the Company entered into an asset purchase agreement with Melt (the “Melt Asset Purchase Agreement”). Pursuant to the terms of the Melt Asset Purchase Agreement, Melt was assigned certain intellectual property and related rights from the Company to develop, formulate, make, sell, and sub-license certain Company conscious sedation and analgesia related formulations (collectively, the “Melt Products”). Under the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company up to eight percent (8%) of net sales of the Melt Products while any patent rights remain outstanding, as well as other conditions. In January and March 2019, the Company entered into the Melt Series A Preferred Stock Agreement.

In February 2019, the Company and Melt entered into a Management Services Agreement (the “Melt MSA”), whereby the Company provides to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt pays the Company a monthly amount of \$10.

As of March 31, 2019, the Company was due \$677 from Melt for reimbursable expenses and amounts due under the Melt MSA and included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets.

The Company’s Chief Executive Officer, Mark L. Baum, and Chief Financial Officer, Andrew Boll, are members of the Melt board of directors, and several employees of the Company (including Mr. Baum and Mr. Boll) entered into consulting agreements and provided consulting services to Melt.

The unaudited condensed results of operations information of Melt is summarized below:

	For the Three months ended March 31, 2019
Revenues, net	\$ -
Loss from operations	647
Net loss	<u>\$ (647)</u>

The unaudited condensed balance sheet information of Melt is summarized below:

	March 31, 2019
Current assets	\$ 10,269
Non current assets	2
Total assets	<u>\$ 10,271</u>
Total liabilities	\$ 950
Total preferred stock and stockholders' equity	9,321
Total liabilities and stockholders' equity	<u>\$ 10,271</u>

#### NOTE 5. INVESTMENT IN SURFACE PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

In 2017 and amended in April 2018, the Company entered into two asset purchase and license agreements (the "Surface License Agreements") with Surface. Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights to develop, formulate, make, sell, and sub-license formulations of certain topical eye drop formulations that utilize a proprietary delivery vehicle and a proprietary doxycycline capsule (collectively, the "Surface Products"). Surface is required to make royalty payments to the Company of four to six percent (4%-6%) of net sales of the Surface Products while any patent rights remain outstanding.

In January 2018, the Company and Surface entered into an amended Management Services Agreement (the "Surface MSA"), whereby the Company provided to Surface certain administrative services and support, including bookkeeping, web services and human resources related activities, and Surface paid the Company a monthly amount of \$10. The Surface MSA was terminated effective July 31, 2018.

As of March 31, 2019, the Company was due \$50 from Surface for reimbursable expenses and amounts due under the Surface MSA and included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets.

As of March 31, 2019, the Company owned 3,500,000 shares of Surface common stock (approximately 30% issued and outstanding equity interests). The Company's director, Richard L. Lindstrom and the Company's Chief Executive Officer, Mark L. Baum, are directors of Surface. In addition, the Company's Chief Financial Officer, Andrew R. Boll, was a director of Surface and resigned as a director of Surface concurrent with the sale of the Surface Series A Stock. Several employees and a director of the Company (including Mr. Baum, Dr. Lindstrom and Mr. Boll) entered into consulting agreements and provided consulting services to Surface. Surface is required to make royalty payments to Dr. Lindstrom of three percent (3%) of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a principal of Flying L Partners, an affiliate of the funding investor.

The unaudited condensed results of operations information of Surface is summarized below:

	For the Three Months Ended March 31, 2019
Revenues, net	\$ -
Loss from operations	812
Net loss	<u>\$ (812)</u>

The unaudited condensed balance sheet information of Surface is summarized below:

	March 31, 2019
Current assets	\$ 18,742
Non current assets	49
<b>Total assets</b>	<b>\$ 18,791</b>
Total liabilities	\$ 396
Total stockholders' equity	18,395
<b>Total liabilities and stockholders' equity</b>	<b>\$ 18,791</b>

#### NOTE 6. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of March 31, 2019 and December 31, 2018 was as follows:

	March 31, 2019	December 31, 2018
Raw materials	\$ 1,499	\$ 1,119
Work in progress	215	6
Finished goods	674	709
<b>Total inventories</b>	<b>\$ 2,388</b>	<b>\$ 1,834</b>

#### NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	March 31, 2019	December 31, 2018
Prepaid insurance	\$ 175	\$ 328
Other prepaid expenses	618	334
Receivable due from Surface	50	50
Receivable due from Melt	677	-
Deposits and other current assets	138	125
<b>Total prepaid expenses and other current assets</b>	<b>\$ 1,658</b>	<b>\$ 837</b>

#### NOTE 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	March 31, 2019	December 31, 2018
Property, plant and equipment, net:		
Computer software and hardware	\$ 1,674	\$ 1,662
Furniture and equipment	381	397
Lab and pharmacy equipment	3,356	3,184
Leasehold improvements	5,585	5,496
	10,996	10,739
Accumulated depreciation and amortization	(4,754)	(4,364)
	<b>\$ 6,242</b>	<b>\$ 6,375</b>

For the three months ended March 31, 2019, depreciation related to the property, plant and equipment was \$390.

## NOTE 9. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at March 31, 2019 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	\$ 862	\$ (53)	\$ -	\$ 809
Licenses	20 years	50	(4)	-	46
Trademarks	Indefinite	327	-	-	327
Customer relationships	3-15 years	2,998	(1,064)	(15)	1,919
Trade name	5 years	16	(15)	(1)	-
Non-competition clause	3-4 years	294	(274)	(20)	-
State pharmacy licenses	25 years	45	(6)	(28)	11
		<u>\$ 4,592</u>	<u>\$ (1,416)</u>	<u>\$ (64)</u>	<u>\$ 3,112</u>

Amortization expense for intangible assets for the three months ended March 31, 2019 was as follows:

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Patents	\$ 4	\$ 7
Licenses	4	-
Customer relationships	51	50
Trade name	2	2
Non-competition clause	-	1
State pharmacy licenses	1	-
	<u>\$ 62</u>	<u>\$ 60</u>

Estimated future amortization expense for the Company's intangible assets at March 31, 2019 is as follows:

Remainder of 2019	\$ 188
2020	247
2021	247
2022	247
2023	247
Thereafter	1,936
	<u>\$ 3,112</u>

There have been no changes in the carrying value of the Company's goodwill during the three months ended March 31, 2019.

**NOTE 10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
Accounts payable	\$ 5,326	\$ 5,606
Accrued litigation settlement (see Note 14)	640	-
Deferred rent	-	388
Accrued interest	177	256
Accrued exit fee for note payable	800	800
Total accounts payable and accrued expenses	6,943	7,050
Less: Current portion	(6,143)	(6,250)
Non-current total accrued expenses	<u>\$ 800</u>	<u>\$ 800</u>

**NOTE 11. DEBT**

At March 31, 2019, future minimum payments under the Company's note payable were as follows:

	<b>Amount</b>
Remainder of 2019	\$ 3,721
2020	4,402
2021	4,033
2022	7,411
Total minimum payments	19,567
Less: amount representing interest	(4,317)
Notes payable, gross	15,250
Less: unamortized discount	(1,347)
	13,903
Less: current portion, net of unamortized discount	(2,552)
Note payable, net of current portion and unamortized debt discount	<u>\$ 11,351</u>

For the three months ended March 31, 2019, debt discount amortization related to note payable was \$125.

**NOTE 12. LEASES**

The Company adopted Topic 842 on January 1, 2019. Topic 842 allows the Company to elect a package of practical expedients, which include: (i) an entity need not reassess whether any expired or existing contracts are or contain leases; (ii) an entity need not reassess the lease classification for any expired or existing leases; and (iii) an entity need not reassess any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize the package of practical expedients and has not elected the hindsight methodology in its implementation of Topic 842.

The Company elected to adopt this standard using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. With the adoption of Topic 842, the Company's condensed consolidated balance sheet now contains the following line items: Right-of-use assets, Operating lease liabilities—short-term and Operating lease liabilities—long-term.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2019:

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021, with an option to extend the term for a five-year period;
- An operating lease for 4,500 square feet of office and lab space in Irvine, California that expires in December 2020, with an option to extend the term for up to two five-year periods; and
- An operating lease for 25,000 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2024, with an option to extend the term for two additional five-year periods.

The extensions within the San Diego, California and Ledgewood, New Jersey operating lease agreements were included within the Company's calculation of the new lease standard as the Company is reasonably certain it will exercise its option to extend these leases. The Company has elected to not recognize right-of-use assets and lease liabilities arising from short-term leases, which are leases that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

The previously classified capital leases are now existing leases classified as finance leases under the new standard. The Company has determined that the identified finance leases did not contain non-lease components and require no further allocation of the total lease cost. The Company has determined that the identified operating leases did contain non-lease components and elected an accounting policy to combine non-lease and lease components to determine the total lease cost. Additionally, the operating agreements in place did not contain information to determine the rate implicit in the leases. As such, the Company calculated the incremental borrowing rate based on the assumed remaining lease term for each lease in order to calculate the present value of the remaining lease payments. At March 31, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.36% and 12.05 years, respectively.

Upon adoption of Topic 842, the Company recorded a \$6,325 increase in operating lease right-of-use assets, a \$388 decrease in accounts payable and accrued expenses and a \$6,712 increase in operating lease liability. The Company did not record any cumulative effect adjustments to opening stockholders' equity. As of March 31, 2019, right-of-use assets and liabilities arising from operating leases were \$6,195 and \$6,594, respectively. During the three months ended March 31, 2019, cash paid for amounts included for the operating lease liabilities was \$223 and the Company recorded operating lease expense of \$234 included in selling, general and administrative expenses.

Future lease payments under operating leases as of March 31, 2019 were as follows:

	<b>Operating Leases</b>
Remainder of 2019	\$ 681
2020	930
2021	809
2022	824
2023	843
Thereafter	5,304
<b>Total minimum lease payments</b>	<b>9,391</b>
Less: amount representing interest payments	(2,797)
<b>Total operating lease liabilities</b>	<b>6,594</b>
Less: current portion, operating lease liabilities	(511)
<b>Operating lease liabilities, net of current portion</b>	<b>\$ 6,083</b>

The Company also has two additional finance leases that are included in its lease accounting but are not considered significant.

Future lease payments under non-cancelable finance leases as of March 31, 2019 were as follows:

	<b>Finance Leases</b>
Remainder of 2019	\$ 565
2020	9
2021	9
2022	9
2023	10
Total minimum lease payments	602
Less: amount representing interest payments	(11)
Present value of future minimum lease payments	591
Less: unamortized discount	(6)
	585
Less: current portion, net of unamortized discount	(553)
Finance lease obligation, net of current portion	<u>\$ 32</u>

At March 31, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the finance leases held by the Company were 9.82% and 0.82 years, respectively.

For the three months ended March 31, 2019, debt discount amortization related to a finance lease obligation was \$10, and included in interest expense, net.

For the three months ended March 31, 2019, depreciation expense related to the equipment held under the finance lease obligations was \$73.

For the three months ended March 31, 2019, cash paid and expense recognized for interest expense related to the finance lease obligation was \$11.

Future minimum lease payments under operating leases and future minimum finance lease payments as of December 31, 2018 were as follows (in thousands):

	<u>Finance Leases</u>	<u>Operating Leases</u>
2019	\$ 751	\$ 797
2020	-	857
2021	-	742
2022	-	320
2023	-	330
Thereafter	-	196
	<u>\$ 751</u>	<u>\$ 3,242</u>
Less: Amounts representing interest	(15)	
Less: Amounts representing unamortized discount	(16)	
Total obligation under capital leases	720	
Less: Current portion of capital leases	(720)	
Long term capital lease obligation	<u>\$ -</u>	

### NOTE 13. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

#### Common Stock

In March 2019, the Company issued 15,000 shares of its restricted common stock, with a fair value of \$75, for commission expenses incurred during the three months ended March 31, 2019.

During the three months ended March 31, 2019, the Company issued 273,984 shares of its common stock related to the cashless exercise of 384,000 common stock warrants with an exercise price of \$1.79.

During the three months ended March 31, 2019, the Company issued 90,055 shares of its common stock related to the exercise of 90,055 common stock warrants with an exercise price of \$1.79, and received net proceeds of \$162.

During the three months ended March 31, 2019, 34,090 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

#### Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan (the "2017 Plan" together with the 2007 Plan, the "Plans"). As of March 31, 2019, the 2017 Plan provides for the issuance of a maximum of 2,000,000 shares of the Company's common stock. The purpose of the Plans are to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plans, the Company is authorized to issue

incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options, restricted stock units and restricted stock. The Plans are administered by the Compensation Committee of the Company's Board of Directors. The Company had 1,146,640 shares available for future issuances under the 2017 Plan at March 31, 2019.

## Stock Options

A summary of stock option activity under the Plans for the three months ended March 31, 2019 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2019	2,482,009	\$ 5.10		
Options granted	291,000	\$ 6.30		
Options exercised	-	\$ -		
Options cancelled/forfeit	(44,287)	\$ 6.24		
Options outstanding - March 31, 2019	<u>2,728,722</u>	\$ 5.21	5.76	\$ 5,994
Options exercisable	<u>1,398,665</u>	\$ 4.74	6.02	\$ 3,763
Options vested and expected to vest	<u>2,604,215</u>	\$ 5.17	5.78	\$ 5,815

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on March 31, 2019, based on the closing price of the Company's common stock of \$4.98 on that date.

During the three months ended March 31, 2019, the Company granted stock options to certain employees. The stock options were granted with an exercise price equal to the current market price of the Company's common stock, as reported by the securities exchange on which the common stock was then listed, at the grant date and have contractual terms of 10 years. Vesting terms for options granted to employees and consultants during the three months ended March 31, 2019 typically included one of the following vesting schedules: 25% of the shares subject to the option vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over three years; and 100% of the shares subject to the option vest on a quarterly basis in equal installments over three years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plan) and in the event of certain modifications to the option award agreement.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. Beginning on April 1, 2018, the Company began calculating expected volatility based solely on the historical volatilities of the common stock of the Company. In the past, the expected volatility was based on the historical volatilities of the common stock of the Company and comparable publicly traded companies, the Company previously utilized this methodology based on its estimate that it had limited relevant historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The expected term of options granted to employees and directors was determined in accordance with the "simplified approach," as the Company has limited, relevant, historical data on employee exercises and post-vesting employment termination behavior. The expected risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. For option grants to employees and directors, the Company assigns a forfeiture factor of 10%. These factors could change in the future, which would affect the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant.

The table below illustrates the fair value per share determined by the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	<b>2019</b>
Weighted-average fair value of options granted	\$ 3.71
Expected terms (in years)	5.8 - 6.1
Expected volatility	64% - 67%
Risk-free interest rate	2.54% - 2.68%
Dividend yield	-

The following table summarizes information about stock options outstanding and exercisable at March 31, 2019:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$1.47 - \$2.60	828,748	7.48	\$ 2.04	479,534	\$ 2.13	
\$2.76 - \$4.22	535,871	6.73	\$ 3.96	449,399	\$ 3.98	
\$5.61 - \$6.30	390,350	8.47	\$ 6.21	98,096	\$ 5.97	
\$6.64 - \$8.99	968,723	2.69	\$ 8.00	366,606	\$ 8.24	
\$42.80	5,030	1.37	\$ 42.80	5,030	\$ 42.80	
\$1.47 - \$42.80	<u>2,728,722</u>	5.76	\$ 5.21	<u>1,398,665</u>	\$ 4.74	

As of March 31, 2019, there was approximately \$3,513 of total unrecognized compensation expense related to unvested stock options granted under the Plans. That expense is expected to be recognized over the weighted-average remaining vesting period of 1.3 years. The stock-based compensation expense for all stock options was \$283 during the three months ended March 31, 2019.

#### Restricted Stock Units

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market-based vesting criteria. The grant date fair value of the RSUs, which has been determined based upon the market value of the Company's common stock on the grant date, is expensed over the vesting period of the RSUs. Unvested portions of RSUs issued to consultants are remeasured on an interim basis until vesting criteria is met.

During the three months ended March 31, 2019, 135,000 RSUs with a fair market value of \$851 were issued to certain employees; the RSUs vest in full on the third year anniversary of the grant date.

A summary of the Company's RSU activity and related information for the three months ended March 31, 2019 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2019	1,275,680	\$ 2.16
RSUs granted	135,000	\$ 6.30
RSUs vested	(34,090)	\$ 2.20
RSUs cancelled/forfeit	-	
RSUs unvested at March 31, 2019	<u>1,376,590</u>	\$ 2.56

As of March 31, 2019, the total unrecognized compensation expense related to unvested RSUs was approximately \$1,900, which is expected to be recognized over a weighted-average period of 0.3 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three months ended March 31, 2019 was \$430.

## Warrants

From time to time, the Company issues warrants to purchase shares of the Company's common stock to investors, lenders, underwriters, settlement agreements and other non-employees for services rendered or to be rendered in the future.

A summary of warrant activity for the three months ended March 31, 2019 is as follows:

	<u>Number of Shares Subject to Warrants Outstanding</u>	<u>Weighted Avg. Exercise Price</u>
Warrants outstanding - January 1, 2019	2,206,973	\$ 1.91
Granted	-	
Exercised	(474,055)	1.79
Expired	-	
Warrants outstanding and exercisable - March 31, 2019	<u>1,732,918</u>	\$ 1.94
Weighted average remaining contractual life of the outstanding warrants in years - March 31, 2019	<u>2.79</u>	

A list of the warrants outstanding as of March 31, 2019 is included in the following table:

Warrant Series	Issue Date	Warrants Outstanding and Exercisable		
		Warrants Outstanding	Exercise Price	Expiration Date
Lender warrants	5/11/2015	125,000	\$ 1.79	5/11/2025
Settlement warrants	8/16/2016	40,000	\$ 3.75	8/16/2021
PIPE investor and placement agent warrants	12/27/2016	952,532	\$ 1.79	12/27/2019
Lender warrants	7/19/2017	615,386	\$ 2.08	7/19/2024
		<u>1,732,918</u>	\$ 1.94	

## Subsidiary Stock-Based Transactions

### *Mayfield Pharmaceuticals, Inc.*

In February 2019, the Company agreed to issue 1,000,000 shares of Mayfield's common stock to Elle in connection with acquisition of certain drug candidate intellectual property and rights. Following the issuance of Mayfield common stock to Elle, and as of March 31, 2019, the Company owned 72% of the equity interests in Mayfield. Mayfield is a consolidated subsidiary; the Company reports the operating results of Mayfield and allocates the noncontrolling interests to the non-majority partners.

## Stock-Based Compensation Summary

The Company recorded stock-based compensation related to equity instruments granted to employees, directors and consultants as follows:

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Employees - selling, general and administrative	\$ 638	593
Directors - selling, general and administrative	75	50
Consultants - selling, general and administrative	75	108
Total	\$ 788	\$ 751

## NOTE 14. COMMITMENTS AND CONTINGENCIES

### *Dr. Sobol*

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against the Company, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via the Company’s alleged transmittal of advertisements to its clients via facsimile. In June 2018, Sobol filed a motion for class certification and in July 2018 the Company filed a response in opposition to the motion for class certification. A hearing on class certification was heard in October 2018, however, prior to a decision regarding class certification was made, in February 2019, the Company entered into a proposed settlement agreement to award the proposed class up to \$1,400 in damages. Due to the nature of the lawsuit and claims, the Company expects total damages related to this lawsuit will total approximately \$640. The Company expects the Court will rule to accept the settlement agreement in the spring of 2019. The Company accrued an expense of \$640 (see Note 10), its estimated damages related to the settlement agreement, during the year ended December 31, 2018.

### *Allergan USA*

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against the Company, primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The parties each filed a motion for summary judgment and *Imprimis* also filed a motion to stay. The parties’ motions were heard on March 26, 2019, with both parties motions being partially granted. The trial date to determine damages, if any, is currently set for May 2019. The Company believes the claims for damages are meritless, and intends to vigorously defend against Allergan’s allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

### *Novel Drug Solutions et al.*

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against the Company in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between the Company and NDS entered into in 2013. In July 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In October 2018, the Company filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. The lawsuit is currently in the discovery phase. The Company believe the claims are meritless and have previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

### *California Board of Pharmacy*

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation the Company believes was legally dispensed and was, without its knowledge, inappropriately administered to a patient unknown to Park, by the prescribing healthcare professional. Park filed a response to the accusation and requested a formal hearing. In April 2019, Park agreed to and the California Board of Pharmacy approved terms of a settlement agreement (the “Settlement Agreement”) that will become effective on or near May 29, 2019. Pursuant to the terms of the Settlement Agreement, Park will be required to surrender Park’s California pharmacy license by August 27, 2019; provided however, in the event of a sale of Park, the California Board of Pharmacy has agreed to expedite the issuance of a temporary license to the Park acquiror. In the event Park is not sold, the Company intends to transfer substantially all of the Park business and related revenues to its New Jersey based pharmacy.

## **Product and Professional Liability**

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. The Company utilizes traditional third-party insurance policies with regard to its product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

### *John Erick et al.*

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming the Company as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various Spectrum entities. The cross-complaint seeks indemnity and contribution from the Company and Spectrum. The Company answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend itself against these allegations. The Company cannot predict the eventual outcome of this litigation. Nonetheless, the litigation process could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

### *General and Other*

In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert its rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject the Company to litigation.

## **Indemnities**

In addition to the indemnification provisions contained in the Company’s charter documents, the Company generally enters into separate indemnification agreements with each of the Company’s directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys’ fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual’s status or service as the Company’s director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. The Company also indemnifies its lessors in connection with its facility leases for certain claims arising from the use of the facilities. These indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities in the accompanying condensed consolidated balance sheets.

## **Klarity License Agreement – Related Party**

In April 2017 and as amended in April 2018, the Company entered into a license agreement (the “Klarity License Agreement”) with Richard L. Lindstrom, M.D., a member of its Board of Directors. Pursuant to the terms of the Klarity License Agreement, the Company licensed certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license the topical ophthalmic solution Klarity used to protect and rehabilitate the ocular surface (the “Klarity Product”).

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% - 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of \$50 upon execution of the Klarity License Agreement, (ii) a second payment of \$50 following the first \$50 in net sales of the Klarity Product; and (iii) a final payment of \$50 following the first \$100 in net sales of the Klarity Product. All of the above referenced milestone payments are payable at the Company's election in cash or shares of the Company's restricted common stock. Payments totaling \$15 were made during the three months ended March 31, 2019. \$22 was incurred as royalty expense during the three months ended and included in accounts payable to Dr. Lindstrom at March 31, 2019.

### **Sales and Marketing Agreements**

During 2017, the Company entered various sales and marketing agreements with certain organizations, to provide exclusive sales and marketing representation services to Harrow in select geographies in the U.S., in connection with our ophthalmic compounded formulations.

Under the terms of the sales and marketing agreements, the Company is required to make commission payments to equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company's restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms, as applicable. \$75 of stock-based payments were made and \$542 were incurred under these agreements for commission expenses during the three months ended March 31, 2019.

### **Asset Purchase, License and Related Agreements**

The Company has acquired and sourced intellectual property rights related to certain proprietary innovations from certain inventors and related parties (the "Inventors") through multiple asset purchase agreements, license agreements, strategic agreements and commission agreements. In general, these agreements provide that the Inventors will cooperate with the Company in obtaining patent protection for the acquired intellectual property and that the Company will use commercially reasonable efforts to research, develop and commercialize a product based on the acquired intellectual property. In addition, the Company has acquired a right of first refusal on additional intellectual property and drug development opportunities presented by these Inventors.

In consideration for the acquisition of the intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of certain milestones, generally consisting of: (1) a payment payable within 30 days after the issuance of the first patent in the United States arising from the acquired intellectual property (if any); (2) a payment payable within 30 days after the Company files the first investigational new drug application ("IND") with the FDA for the first product arising from the acquired intellectual property (if any); (3) for certain of the Inventors, a payment payable within 30 days after the Company files the first new drug application with the FDA for the first product arising from the acquired intellectual property (if any); and (4) certain royalty payments based on the net receipts received by the Company in connection with the sale or licensing of any product based on the acquired intellectual property (if any), after deducting (among other things) the Company's development costs associated with such product. If, following five years after the date of the applicable asset purchase agreement, the Company either (a) for certain of the Inventors, has not filed an IND or, for the remaining Inventors, has not initiated a study where data is derived, or (b) has failed to generate royalty payments to the Inventors for any product based on the acquired intellectual property, the Inventors may terminate the applicable asset purchase agreement and request that the Company re-assign the acquired technology to the Inventors. \$191 and \$83 were incurred under these agreements as royalty expenses for the three months ended and included in accounts payable at March 31, 2019 and 2018, respectively.

### **NOTE 15. SEGMENT INFORMATION AND CONCENTRATIONS**

Beginning on January 1, 2019, the Company began evaluating performance of the Company based on operating segments. Segment performance for its two operating segments are based on segment contribution. The Company's reportable segments consist of (i) its commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of ImprimisRx and Park Compounding businesses; and (ii) its start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the three months ended March 31, 2019:

	For the Three Months Ended March 31, 2019		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 12,290	\$ -	\$ 12,290
Cost of sales	(3,898)	-	(3,898)
Gross profit	8,392	-	8,392
<b>Operating expenses:</b>			
Selling, general and administrative	5,715	43	5,758
Research and development	125	136	261
<b>Segment contribution</b>	<u>2,552</u>	<u>(179)</u>	<u>2,373</u>
Corporate, selling, general and administrative			2,719
Research and development			144
Amortization of intangible assets			66
Operating loss			<u>\$ (556)</u>

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues are attributed to the U.S. All long-lived assets at March 31, 2019 and December 31, 2018 are located in the U.S.

The Company sells its compounded formulations to a large number of customers. There were no customers who comprised more than 10% of the Company's total pharmacy sales for the three months ended March 31, 2019 and 2018.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 67% and 58% of active pharmaceutical ingredient purchases during the three months ended March 31, 2019 and 2018, respectively.

#### NOTE 16. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to March 31, 2019 through the filing date of this Quarterly Report. Based on its evaluation, no other events as than those described below need to be disclosed.

On May 6, 2019, the Company entered into an Asset Purchase Agreement with Eton (the "CT APA") to re-acquire assets related to its synthetic corticotropin formulation from Eton (CT-100). The CT APA requires royalty on net sales of 3%, subject to adjustments, and milestone payments that allow for three separate payments of \$100, \$200 and \$700 to Eton (\$1,000, in aggregate) upon submission of an investigational new drug application, regulatory approval and at the point when cumulative net sales of the CT-100 exceed \$50,000, respectively.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto contained in Part I, Item 1 of this Quarterly Report on Form 10-Q (this “Quarterly Report”). Our condensed consolidated financial statements have been prepared and, unless otherwise stated, the information derived therefrom as presented in this discussion and analysis is presented, in accordance with accounting principles generally accepted in the United States of America (“GAAP”).*

*The information contained in this Quarterly Report is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (the “SEC”), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and subsequent reports on Form 8-K, which discuss our business in greater detail. As used in this discussion and analysis, unless the context indicates otherwise, the terms the “Company”, “Harrow” “we”, “us” and “our” refer to Harrow Health, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., ImprimisRx, LLC, Imprimis Rx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, Radley Pharmaceuticals, Inc., and Mayfield Pharmaceuticals, Inc. In this discussion and analysis, we refer to our consolidated subsidiaries collectively as our “ImprimisRx compounding pharmacies.”*

*In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as “will”, “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “forecasts”, “potential” or “continue” or the negative of these terms or other comparable terminology. All statements made in this Quarterly Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading “Risk Factors” in Part II, Item 1A of this Quarterly Report. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made and, except as required by law, we undertake no obligation to revise or publicly update any forward-looking statement for any reason.*

### Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. Prior to 2017, the Company’s business was primarily focused on its ImprimisRx business, the nation’s leading ophthalmology pharmaceutical compounding business, and Park Compounding, Inc. (“Park”), a leading health and wellness compounding business. Since 2017, in addition to wholly-owning ImprimisRx and Park, we also have founded and have continuing equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”). In 2018, the Company also founded the subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”) and Radley Pharmaceuticals, Inc. (“Radley”). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Surface, Melt, Radley and Mayfield. Harrow intends to continue to pursue its operations through subsidiaries for, and found, and hold equity and royalty rights, in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties

## **Pharmaceutical Compounding Businesses**

### ***Pharmaceutical Compounding***

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the U.S. Food and Drug Administration (“FDA”) (either as a finished form product or as a bulk drug ingredient) and excipients, to create specialized pharmaceutical preparations. Physicians and healthcare institutions use compounded drugs when commercially available drugs do not optimally treat a patient’s needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician’s diagnosis and a fair price and great service for a quality pharmaceutical product. We sell our products through a network of employees and independent contractors and we dispense our formulations in all 50 states, Puerto Rico and in selected markets outside the United States.

### ***ImprimisRx***

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer our thousands of physician customers and their patients critical medicines to meet needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacies, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other FDA guidance documents, in our FDA-registered outsourcing facility (“NJOF”).

### ***Park Compounding***

Park, our wholly owned subsidiary pharmacy based in Irvine, California, is focused on primarily health and wellness related, customizable pharmaceutical compounding. Park dispenses sterile and non-sterile compounded medications prescribed by licensed practitioners when commercially available choices do not meet a patient’s needs. Park also produces and dispenses certain of our ophthalmology-based formulations.

## **Pharmaceutical Development Businesses**

We have ownership interests in Eton, Surface, Melt, Mayfield and Radley and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application (NDA) where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In 2018, we formed and created subsidiaries named Radley and Mayfield, which we intend to operate similar to Eton, Surface and Melt. In addition, we intend to create additional subsidiaries that will be focused on the development and FDA approval of certain proprietary drug formulations that we currently own, will in-license/acquire and/or otherwise develop.

### ***Eton Pharmaceuticals, Inc.***

Eton is a pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA’s 505(b)(2) regulatory pathway. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. Eton’s pipeline is focused on innovative 505(b)(2) products and obtaining FDA marketing approval for currently marketed but unapproved drugs.

In May 2017, Eton closed an offering of its Series A Preferred Stock and we lost our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. We own 3,500,000 shares of Eton common stock, which we estimate is approximately 19.86% of the equity and voting interests issued and outstanding of Eton as of March 31, 2019.

#### ***Surface Pharmaceuticals, Inc.***

Surface is a development-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases and is seeking FDA approval for the commercialization of its drug candidates through the Section 505(b)(2) regulatory pathway under the FDCA. In 2017 and amended in April 2018, Harrow entered into asset purchase and license agreements (the “Surface License Agreements”) and transferred to Surface its current drug pipeline, which consists of three proprietary drug candidates. Surface’s patent-pending topical eye drop drug candidates, SURF-100 and SURF-200, utilize a patented delivery vehicle known as Klarity Drops (“Klarity”), that was invented by Harrow board member and Surface’s chairman of the board and renowned ophthalmologist Dr. Richard Lindstrom. Klarity is designed to protect and rehabilitate the ocular surface pathology for patients with dry eye disease, or DED. Surface’s drug candidate SURF-300 is a patent-pending oral capsule that will target patients also suffering from DED signs and symptoms.

In May and July 2018, Surface closed on an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. We own 3,500,000 shares of Surface which we estimate is approximately 30% of the equity and voting interests.

#### ***Melt Pharmaceuticals, Inc.***

Melt is a development-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the FDA’s 505(b)(2) regulatory pathway for its proprietary technologies, where possible. In December 2018, we entered into an Asset Purchase Agreement with Melt (the “Melt Asset Purchase Agreement”), and Harrow assigned to Melt the underlying intellectual property for Melt’s current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company up to eight percent (8%) of net sales of products described in the Melt Asset Purchase Agreement, while any patent rights remain outstanding, as well as other conditions.

During January and March 2019, Melt closed on the sale of its Series A Preferred Stock. At the time of the closing of the Melt Series A Round, we lost our controlling interest, and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which we estimate is approximately 44% of the equity and voting interests.

#### ***Mayfield Pharmaceuticals, Inc.***

Mayfield, a consolidated subsidiary of Harrow, is a development-stage women’s and men’s health-focused pharmaceutical company. Mayfield intends to seek regulatory approval through the FDA’s 505(b)(2) regulatory pathway for its proprietary drug candidates and technologies, including its lead drug candidate MAY-44. MAY-44 is non-estrogen topical analgesic gel containing a patented pH-balanced formulation of 3.75% lidocaine and other essential excipients designed for use on mucosal surfaces. If FDA-approved, MAY-44 could become the first topical product indicated for dyspareunia. A more recent estimates suggest dyspareunia affects greater than one in ten women (BJOG An International Journal of Obstetrics and Gynecology 2017).

Mayfield and Harrow acquired the intellectual property associated with MAY-44 in January 2019 from Elle Pharmaceutical LLC (the “Mayfield Asset Purchase Agreement”) in exchange for \$25,000, with an additional \$175,000 due upon third party financing of Mayfield, 1,000,000 shares of Mayfield common stock and a 7.5% royalty rate on sales of the product. Once we have finalized the drug candidate assets Mayfield will seek to build out the Mayfield management, board and clinical advisory team. We own 2,500,000 shares of Mayfield common stock, which is 72% of the equity and voting interests issued and outstanding of Mayfield. We intend to pursue a deconsolidating transaction for Mayfield during 2019.

## ***Radley Pharmaceuticals, Inc.***

Radley, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on the development of proprietary 505(b)(2) drug candidates focused on rare diseases. Radley currently has three proprietary drug candidates in its pipeline. During 2019, and prior to initiating significant development activities and costs related to these drug candidates, we intend to meet with FDA to establish and understand the expected clinical and regulatory path to approval for these drug candidates. We are also pursuing investigator-initiated studies for some of Radley's drug candidates with well-known healthcare institutions. We believe this approach will allow us to better understand and weigh the economic costs, clinical feasibility and potential benefits associated with pursuing development activities associated with these drug candidates.

### **Factors Affecting Our Performance**

We believe the primary factors affecting our performance are our ability to increase revenues of our proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our pharmacy operations, optimize pricing and obtain reimbursement options for our proprietary compounded formulations, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other assets that we have not yet made commercially available as compounded formulations. We believe we have built a tangible and intangible infrastructure that will allow us to scale revenues efficiently in the long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See “—Liquidity and Capital Resources” below.

### ***Reimbursement Options***

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. We are communicating with government and third-party payors in order to make our formulations available to more patients and at optimized pricing levels. However, if government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance and opportunity for our formulations may be limited.

### **Recent Developments**

The following describes certain developments in 2019 to date that are important to understand our financial condition and results of operations. See the notes to our condensed consolidated financial statements included in this report for additional information about each of these developments.

#### ***Melt Pharmaceuticals Asset Purchase Agreement and Series A Round***

As described more fully above under the sub-heading “Melt Pharmaceuticals, Inc.”, we entered into the Melt Asset Purchase Agreement with our previously wholly owned subsidiary, Melt. Following the close of the Melt Series A Round, we lost controlling interest in Melt. Pursuant to the terms of the Melt Asset Purchase Agreement, we assigned and licensed to Melt certain intellectual property and related rights to develop, formulate, make, sell, and sublicense its current drug candidate pipeline.

## Mayfield Pharmaceuticals Asset Purchase Agreement

As described more fully above under the sub-heading “Mayfield Pharmaceuticals, Inc.”, in February 2019, we along with our subsidiary, Mayfield, entered the Mayfield Asset Purchase Agreement with Elle Pharmaceuticals, Inc. to acquire intellectual property associated with its drug candidate, MAY-44.

### Results of Operations

The following period-to-period comparisons of our financial results are not necessarily indicative of results for the current period or any future period.

#### Comparison of the three months ended March 31, 2019 and 2018

##### Revenues

Our revenues include amounts recorded from sales of proprietary compounded formulations and revenues received from royalty payments owed to us pursuant to out-license arrangements.

The following presents our revenues for the three months ended March 31, 2019 and 2018:

	For the Three months ended March 31,		\$ Variance
	2019	2018	
Product sales, net	\$ 12,283,000	\$ 8,855,000	\$ 3,428,000
License revenues	7,000	10,000	(3,000)
<b>Total revenues</b>	<b>\$ 12,290,000</b>	<b>\$ 8,865,000</b>	<b>\$ 3,425,000</b>

The increase in revenue between periods was largely attributable to increased sales of our proprietary formulations and furtherance of our ophthalmology-related compounded formulations. Our gross ophthalmology-related sales were approximately \$10,976,000 for the three months ended March 31, 2019, compared to \$6,980,000 during the same period last year. Net revenues generated from NJOF (which include certain ophthalmology-related sales) totaled \$7,398,000 and \$4,589,000 during the three months ended March 31, 2019 and 2018, respectively.

##### Cost of Sales

Our cost of sales includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

The following presents our cost of sales for the three months ended March 31, 2019 and 2018:

	For the Three months ended March 31,		\$ Variance
	2019	2018	
Cost of sales	\$ 3,898,000	\$ 4,071,000	\$ (173,000)

The decrease in our cost of sales between periods was largely attributable to an increase in production efficiency and reduction of waste associated with the costs of such sales.

##### Gross Profit and Margin

	For the Three months ended March 31,		\$ Variance
	2019	2018	
Gross Profit	\$ 8,392,000	\$ 4,794,000	\$ 3,598,000
Gross Margin	68%	54%	14%

The increase in gross profit and gross margin between periods is largely attributable to increased efficiencies in our production process, extension of beyond using dating, or BUD, of some of our products, and utilization of capacities as a result of increased output.

*Selling, General and Administrative Expenses*

Our selling, general and administrative expenses include personnel costs, including wages and stock-based compensation, corporate facility expenses, and investor relations, consulting, insurance, filing, legal and accounting fees and expenses as well as costs associated with our marketing activities and sales of our proprietary compounded formulations and other non-proprietary pharmacy products and formulations.

The following presents our selling, general and administrative expenses for the three months ended March 31, 2019 and 2018:

	<b>For the Three months ended</b>		<b>\$</b>
	<b>March 31,</b>		
	<b>2019</b>	<b>2018</b>	
<b>Selling, general and administrative</b>	<b>\$ 8,543,000</b>	<b>\$ 6,488,000</b>	<b>\$ 2,055,000</b>

The increase in selling, general and administrative expenses between for periods was largely attributable to increased sales commission amounts and legal expenses incurred associated with ongoing litigation.

*Research and Development Expenses*

Our research and development expenses primarily include expenses related to the development of acquired intellectual property, investigator-initiated research and evaluations and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the three months ended March 31, 2019 and 2018:

	<b>For the Three months ended</b>		<b>\$</b>
	<b>March 31,</b>		
	<b>2019</b>	<b>2018</b>	
<b>Research and development</b>	<b>\$ 405,000</b>	<b>\$ 87,000</b>	<b>\$ 318,000</b>

The increase in research and development expenses between periods was primarily attributable to the increase in formulation development studies for new ophthalmic formulations and clinical programs related to our drug development segment during the three months ended March 31, 2019.

*Interest Expense, net*

Interest expense, net was \$603,000 for the three months ended March 31, 2019 compared to \$663,000 during the same period last year. The decrease was primarily due to interest expense recognition related to a decrease in the amortization of our capital lease obligations.

*Investment Gain from Melt, net*

During the three months ended March 31, 2019, we recorded a net gain of \$5,525,000 related to our investment in Melt. We recorded a gain of \$5,810,000 for the deconsolidation of Melt, and a loss of \$285,000 for our share of losses based on our ownership of Melt. We began using equity method accounting for our investment in Melt beginning on January 30, 2019, the date we no longer had a controlling interest, prior to that date, their losses were consolidated within our statements of operations.

### *Investment loss from Surface*

During the three ended March 31, 2019, we recorded a loss of \$243,000, for our share of losses based on our ownership of Surface. We began using equity method accounting for our investment in Surface beginning on June 11, 2018, the date we no longer had a controlling interest, prior to that date, their losses were consolidated within our statements of operations.

### *Investment Gain (Loss) from Eton, net*

We recorded a gain of \$6,580,000 related to the change in fair market value of Eton's common stock for the three months ended March 31, 2019. During the three months ended March 31, 2018, we recorded a loss of \$1,069,000, for our share of losses based on our ownership of Eton. We began recording our investment in Eton at fair market value, and ceased equity method accounting for our investment in Eton, in November 2018 following Eton's IPO and our ownership percent falling below 20%.

### *Other Income, net*

During the three months ended March 31, 2019, we recorded other income, net of \$630,000. This was due to income of \$630,000 related to expenses that were paid by us and reimbursed by Melt following its deconsolidation.

### *Net Income (Loss)*

The following table presents our net income (loss) for the three months ended March 31, 2019 and 2018:

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Net income (loss) attributable to Harrow Health, Inc.	\$ 11,358,000	\$ (3,513,000)
Net income (loss) per share, basic	\$ 0.46	\$ (0.17)
Net income (loss) per share, diluted	\$ 0.43	\$ (0.17)

### **Financial Information About Segments and Geographic Areas**

Beginning on January 1, 2019, we began evaluating performance of the Company based on operating segments. Segment performance for our two operating segments are based on segment contribution. Our reportable segments consist of (i) our commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx and Park Compounding businesses; and (ii) the start-up operations associated with our pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. We do not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

See Note 15 to our condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

## Liquidity and Capital Resources

### Liquidity

Our cash on hand (including restricted cash) at March 31, 2019 was \$4,265,000, compared to \$6,838,000 at December 31, 2018. Since inception through December 31, 2018, we have incurred aggregate losses of \$74,211,000. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for a former drug candidate, which activities we have now discontinued, the development and commercialization of novel compounded formulations and the development of our pharmacy operations.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$4,065,000 and restricted investments of \$200,000 totaling approximately \$4,265,000 at March 31, 2019, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. We also may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton and/or any of our subsidiaries. However, our plans for this period may change, our estimates of our operating expenses, capital expenditures and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

We expect to use our current cash position and funds generated from our operations and any financing to pursue our business plan, which includes developing and commercializing compounded formulations and technologies, integrating and developing our compounding operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, and/or assets or technologies, and otherwise fund our operations. We may also use our resources to conduct clinical trials or other studies in support of our formulations or any drug candidate for which we pursue FDA approval, to pursue additional development programs or to explore other development opportunities.

### Net Cash Flow

The following provides detailed information about our net cash flows for the three months ended March 31, 2019 and 2018:

	<b>March 31 2019</b>	<b>March 31 2018</b>
Net cash used in operating activities	\$ (1,476,000)	\$ (965,000)
Net cash used in investing activities	(324,000)	(264,000)
Net cash used in financing activities	(773,000)	(98,000)
Net change in cash and cash equivalents	(2,573,000)	(1,327,000)
Cash and cash equivalents at beginning of the period	6,838,000	4,219,000
Cash and cash equivalents at end of the year	<u>\$ 4,265,000</u>	<u>\$ 2,892,000</u>

### *Operating Activities*

Net cash used in operating activities was \$(1,476,000) during the three months ended March 31, 2019, as compared to \$(965,000) used in operating activities during the same period in the prior year. The increase in net cash used in operating activities during the periods was mainly attributed to the use of working capital associated with payments for annual bonuses and annual prepaid expenses that occur in the first quarter of the year.

### *Investing Activities*

Net cash used in investing activities during the three months ended March 31, 2019 and 2018 was \$(324,000) and \$(264,000), respectively. Cash used in investing activities in 2019 and 2018, were primarily associated with equipment purchases and upgrades and investments in our intellectual property portfolio.

### *Financing Activities*

Net cash used in financing activities during the three months ended March 31, 2019 and 2018 was \$(773,000) and \$(98,000), respectively. Cash used in financing activities during the three months ended March 31, 2019 was mostly related to principal payment of our note payable.

### **Sources of Capital**

Our principal sources of cash consist of cash provided by operating activities from our pharmaceutical compounding business. We may also sell some or all of our ownership interests in Eton, Surface, Melt or our other subsidiaries. We just recently began producing cash from our operations during 2018, however historically, and during the three months ended March 31, 2019, we haven't received sufficient revenues to support our operations and may not be able to continue to do so.

We may need significant additional capital to support our business plan and fund our proposed business operations. We may receive additional proceeds from the exercise of stock purchase warrants that are currently outstanding. We may also seek additional financing from a variety of sources, including other equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or any other financing transaction. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration or licensing arrangements or sales of assets, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies or formulations, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants included in the agreements governing the loan from SWK Funding, LLC and its partners. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results.

We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals and pharmacy industries, or our operating history, including our past bankruptcy proceedings. In addition, the fact that we have a limited history of profitability could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

## **Recently Issued and Adopted Accounting Pronouncements**

See Note 2 to our condensed consolidated financial statements included in this Quarterly Report.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

## **Item 4. Controls and Procedures**

### ***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted pursuant to the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the “SEC”), and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, as they existed on March 31, 2019. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2019, the end of the period covered by this report.

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

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our quarter ended March 31, 2019, 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**

*Dr. Sobol*

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against us, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via our alleged transmittal of advertisements to our clients via facsimile. In June 2018, Sobol filed a motion for class certification and in July 2018 we filed a response in opposition to the motion for class certification. A hearing on class certification was heard on October 24, 2018, however, prior to a decision regarding class certification was made, in February 2019, we entered into a proposed settlement agreement to award the class up to \$1.4 million in damages. However, due to the nature of the lawsuit and claims, we expect total damages related to this lawsuit will total approximately \$640,000. We expect the Court will rule to accept our settlement agreement in the spring of 2019. We accrued an expense of \$640,000, our estimated damages related to the settlement agreement, during the year ended December 31, 2018.

*Allergan USA*

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against Imprimis Pharmaceuticals, Inc., primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The parties have each filed a motion for summary judgment and Imprimis also filed a motion to stay. The parties’ motions is scheduled to be heard on March 26, 2019. The trial date is currently set for May 2019. We believe the claims for damages are meritless, and intend to vigorously defend against Allergan’s allegations. Nonetheless, we cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm our business and the value of our common stock.

*Novel Drug Solutions et al.*

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against us in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between us and NDS entered into in 2013. In July 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In October 2018, we filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. We are currently in the discovery phase of this lawsuit. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

*California Board of Pharmacy*

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation the Company believes was legally dispensed and was, without its knowledge, inappropriately administered to a patient unknown to Park, by the prescribing healthcare professional. Park filed a response to the accusation and requested a formal hearing. In April 2019, Park agreed to and the California Board of Pharmacy approved terms of a settlement agreement (the “Settlement Agreement”) that will become effective on or near May 29, 2019. Pursuant to the terms of the Settlement Agreement, Park will be required to surrender Park’s California pharmacy license by August 27, 2019; provided however, in the event of a sale of Park, the California Board of Pharmacy has agreed to expedite the issuance of a temporary license to the Park acquiror. In the event Park is not sold, we intend to transfer substantially all of the Park business and related revenues to our New Jersey based pharmacy.

## Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. We utilize traditional third-party insurance policies with regard to our product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

*John Erick et al.*

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against us and various Spectrum entities. The cross-complaint seeks indemnity and contribution from us and Spectrum. We answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

*General and Other*

In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject us to litigation.

### Item 1A. Risk Factors

*You should carefully consider the following risk factors in addition to the other information contained in this Quarterly Report. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks.*

#### Risks Related to Our Business

***Until last year, we have incurred losses in every year of our operations, and we may not be profitable in the future.***

Until 2018, we have incurred losses in every year of our operations, including net income (losses) of \$14,625,000 and \$(11,985,000) for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, our accumulated deficit was \$(62,853,000). Our current projections indicate that we will have operating income and/or net income during 2019; however, these projections may not be correct and our plans could change. Also, we could incur increasing operating losses in the foreseeable future for our commercialization activities, research and development and our pharmaceutical compounding business which would impact net income. Recent changes to the accounting for equity investments require those investments to be measured at fair market value, which may cause our earnings (losses) to become volatile as the stock prices of those equity investments fluctuate. Although we have been generating revenue from our pharmaceutical compounding operations, our ability to generate the revenues necessary to achieve profitability will depend on many factors, including those discussed in this “Risk Factors” section. Our business plan and strategies involve costly activities that are susceptible to failure, and, therefore, we may not be able to generate sufficient revenue to support and sustain our business or reach the level of sales and revenues necessary to achieve and sustain profitability.

***We may not receive sufficient revenue to fund our operations and recover our development costs.***

Our business plan involves the preparation and sale of our proprietary formulations through our compounding pharmacies and outsourcing facilities. We have limited experience operating pharmacies and commercializing compounded formulations, and we may be unable to successfully manage this business or generate sufficient revenue to recover our development costs and operational expenses. We may have only limited success in marketing and selling our proprietary formulations. Although we have established and plan to grow our internal sales teams to market and sell our proprietary formulations and other non-proprietary products, we have limited experience with such activities and may not be able to generate sufficient physician and patient interest in our formulations to generate significant revenue from sales of these products. In addition, we are substantially dependent on our ImprimisRx compounding pharmacies and outsourcing facilities, along with any pharmacy partners with which we may contract to compound and sell our formulations using our quality standards and specifications, in a timely manner and sufficient volumes to accommodate the number of prescriptions they receive. Our pharmacies may be unable to compound our formulations successfully and we may be unable to acquire, build or enter into arrangements with pharmacies or outsourcing facilities of sufficient size, reputation and quality to implement our business plan, which would cause our business to suffer.

***We sell certain of our proprietary formulations primarily through pharmaceutical compounding facilities we own, but we may not be successful in our efforts to integrate these businesses into our operations.***

Our business strategy includes establishing a small compounding pharmacy group, whether through acquisitions, establishing new pharmacies or entering into licensing arrangements with third-party pharmacies and outsourcing facilities, to market and sell our proprietary formulations and other non-proprietary products in all 50 states and in certain geographies outside of the U.S.

We currently have compounding facilities in New Jersey and California. We may plan to expand our pharmacy operations and personnel and developing our facilities into a unified group compounding pharmacy facilities. We have been developing “ImprimisRx” as a uniform brand for certain compounding facilities and ophthalmology focused pharmaceutical compounding business. We have limited experience acquiring, building or operating compounding pharmacies or other prescription dispensing facilities or commercializing our formulations through ownership of or licensing arrangements with pharmacies.. In addition, as we have in the past, we have purchased and operated certain pharmaceutical compounding businesses and pharmacies, and subsequently divested or sold those associated assets, we may pursue similar strategies in the future. Those things considered, we may experience difficulties implementing and/or executing on our compounding pharmacy strategy, including difficulties that arise as a result of our lack of experience, and we may be unsuccessful and our plans may change materially. For instance:

- we have experienced delays and increased costs in our outsourcing facility construction efforts;
- we may not be successful in completing future construction plans on a timely basis or within budget;
- we may not be successful in our efforts to integrate, manage or otherwise realize the benefits we expect from acquisitions of our ImprimisRx compounding pharmacies or any additional pharmacy businesses or outsourcing facilities we to acquire, sell or build in the future;
- we may not be able to satisfy applicable federal and state licensing and other requirements for any of our pharmacy businesses in a timely manner or at all;
- changes to federal and state pharmacy regulations may restrict compounding operations or make them more costly;
- we may be unable to achieve a sufficient physician and patient customer base to sustain our pharmacy operations;
- market acceptance of compounding pharmacies generally may be curtailed or delayed; and
- we may not be able to enter into licensing or other arrangements with third-party pharmacies or outsourcing facilities when desired, on acceptable terms or at all.

Moreover, all our efforts to expand pharmacy operations will involve significant costs and other resources, which we may not be able to afford and may disrupt our other operations and distract management and employees from the other aspects of our business. As a result, our business could materially suffer if we are unable to further develop a group of unified compounding facilities and, even if we are successful, we may be unable to generate sufficient revenue to recover our costs.

***We are dependent on market acceptance of compounding pharmacies and compounded formulations, and physicians may be unwilling to prescribe, and patients may be unwilling to use, our proprietary customizable compounded formulations.***

We currently distribute our proprietary formulations through compounding pharmacies and an outsourcing facility. Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. Thus, our compounded formulations have not undergone the FDA approval process and only limited data, if any, may be available about the safety and efficacy of our formulations for any particular indication. Certain compounding pharmacies have been subject to widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has issued formal requests to compounding pharmacies and outsourcing facilities to conduct a recall of all non-expired, purportedly sterile drug products and to cease sterile compounding operations due to lack of sterility assurance. As a result, some health care providers may be reluctant to purchase and use compounded drugs. Our growth and future sales depend not only on our ability to demonstrate in the face of increased scrutiny the quality and safety of our pharmacies and outsourcing facilities and our compliance with more stringent regulatory standards at the federal and state levels, but also on the continued acceptance of compounded drugs and formulations, particularly outsourced compounded drugs and formulations, in the marketplace.

An incident similar to the fungal meningitis outbreak in 2012, which was caused by a compounding pharmacy employing a non-sterile-to-sterile business model, could cause our customers to reduce their use of compounded formulations significantly or even stop using compounded drugs altogether. States have in the past, and could in the future, enact regulation prohibiting or restricting the use of compounding pharmacies and outsourcing facilities in response to such incidents. Such prohibitions or restrictions by states or reduced customer demand as a result of an incident with compounded drugs and formulations could have a material adverse effect on our business, results of operations and financial condition.

In August 2017, FDA issued a MedWatch notification regarding our curcumin emulsion and two adverse events that had been associated with the use of these emulsions by prescribing physicians. We issued a press release on August 7, 2017, clarifying certain facts regarding the notice which outlined our belief that the adverse events associated with the two patients occurred due to an allergic reaction caused by the products being inappropriately administered and obtained by the prescribing physician, and our use of curcumin and excipients in our curcumin emulsion formulation met regulatory standards required for dispensing of the curcumin emulsion. In September 2017, the FDA released a letter confirming that the alleged misuse of certain ingredients in our curcumin emulsions were due to mislabeling by the underlying supplier, and not of our own misdoing. Separately, in December 2017, we were issued a warning letter from the FDA alleging that, in their interpretation of our public communications, we had made false or misleading claims and omitted risk and side effect information regarding certain of our ophthalmology focused compounded medications. We immediately performed a full review of our public communications referenced in the warning letter and responded to the FDA in January 2018. Notwithstanding our continued belief that our public communications were not in fact false and misleading, we have been in communication with the FDA and are taking steps to address the items outlined in the FDA letter. We will continue to work with the FDA to assure that all allegations in the warning letter have been addressed. We believe, to date, we have addressed all of the material items of concern in the FDA's warning letter and those related to the MedWatch notification (and any other requirements observed by FDA and noted to us), and we do not believe there will be any further action taken by FDA in this matter. Nonetheless, these two items increased further scrutiny and negative publicity on us as a company. At times, we have become aware of negative views of regulators related to certain formulations, and as a result discontinued compounding certain drug formulations in an attempt help mitigate potential regulatory risk. As a result of the MedWatch notice and other regulatory notifications, some physicians may be hesitant to prescribe and some patients may be hesitant to purchase and use non-FDA approved compounded formulations, particularly when an FDA-approved potential alternative is available. For other reasons physicians may be unwilling to prescribe or patients may be unwilling to use our proprietary compounded formulations, including the following: legal proscriptions on our ability to discuss the efficacy or safety of our formulations with potential users to the extent applicable data is available; our pharmacy operations are primarily operating on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the government Medicare and Medicaid programs; and certain formulations are not required to be prepared and are not presently being prepared in a manufacturing facility governed by cGMP requirements. Any failure by physicians, patients and/or third-party payors to accept and embrace compounded formulations could substantially limit our market and cause our operations to suffer.

***Our business is significantly impacted by state and federal statutes and regulations.***

Our proprietary formulations are comprised of active pharmaceutical ingredients that are components of drugs that have received marketing approval from the FDA, although our proprietary compounded formulations have not themselves received FDA approval. FDA approval is not required in order to market and sell our compounded formulations. In the future we may choose to pursue FDA approval to market and sell certain potential drug candidates. The marketing and sale of compounded formulations is subject to and must comply with extensive state and federal statutes and regulations governing compounding pharmacies. These statutes and regulations include, among other things, restrictions on compounding for office use or in advance of receiving a patient-specific prescription or, for outsourcing facilities, requirements regarding preparation, such as regular FDA inspections and cGMP requirements, prohibitions on compounding drugs that are essentially copies of FDA-approved drugs, limitations on the volume of compounded formulations that may be sold across state lines, and prohibitions on wholesaling or reselling. These and other restrictions on the activities of compounding pharmacies and outsourcing facilities may significantly limit the market available for compounded formulations, as compared to the market available for FDA-approved drugs.

Our pharmacy business is impacted by federal and state laws and regulations governing the following: the purchase, distribution, management, compounding, dispensing, reimbursement, marketing and labeling of prescription drugs and related services; FDA and/or state regulation affecting the pharmacy and pharmaceutical industries, including state pharmacy licensure and registration or permit standards; rules and regulations issued pursuant to HIPAA and other state and federal laws related to the use, disclosure and transmission of health information; and state and federal controlled substance laws. Our failure to comply with any of these laws and regulations could severely limit or curtail our pharmacy operations, which would materially harm our business and prospects. Further, our business could be adversely affected by changes in these or any newly enacted laws and regulations, and federal and state agency interpretations of the statutes and regulations. Statutory or regulatory changes could require us to make changes to our business model and operations and/or could require us to incur significantly increased costs to comply with such regulations.

***If one of our pharmacies fails to comply with state statutes and regulations, the pharmacy could be required to cease operations or become subject to restrictions that could adversely affect our business.***

State pharmacy laws require pharmacy locations in those states be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. If one of our pharmacies, or with which we may partner is found not to comply with state pharmacy and controlled substance laws and regulations, the pharmacy could be required to cease operations or become subject to burdensome restrictions and limitations on its business. For example, in March 2018, the California Board of Pharmacy filed an accusation against our subsidiary, Park Compounding, Inc. related to a compounded formulation we believe was legally dispensed and was, without our knowledge, inappropriately administered to a patient unknown to us, by the prescribing healthcare professionals. While we dispute all claims against Park, we did enter into a settlement agreement with the California Board of Pharmacy which may require us to permanently or temporarily cease or limit Park's pharmacy locations operations including its sterile compounding operations. If Park Compounding is required to permanently or temporarily cease or limit its sterile compounding operations, we may transfer its business to our New Jersey based pharmacy, sell Park or look to partner with other pharmacies. Although we distribute our proprietary formulations through other compounding pharmacies, and not solely through Park Compounding, the loss of Park Compounding's ability to compound sterile formulations could have an adverse impact on our ability to implement our business plan in a timely manner.

***If we or our partner facilities fail to comply with the Controlled Substances Act, FDCA, or similar state statutes and regulations, the pharmacy facilities could be required to cease operations or become subject to restrictions that could adversely affect our business.***

State pharmacy laws require pharmacy locations in those states to be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. These laws also subject pharmacies to oversight by state boards of pharmacy and other regulators that could impose burdensome requirements or restrictions on operations if a pharmacy is found not in compliance with these laws. We believe that our compounding pharmacies are in material compliance with applicable regulatory requirements. Further, if any of our compounding pharmacies (including Park) fail to comply with regulatory requirements, they could be forced to permanently or temporarily cease or limit their compounding operations, which would severely limit our ability to market and sell our proprietary formulations and would materially harm our operations and prospects. Any noncompliance could also result in complaints or adverse actions by other state boards of pharmacy. FDA inspection of a facility to determine compliance with the FDCA, if not successful, may result in the loss of FDCA exemptions provided under Sections 503A and 503B, warning letters, injunctions, prosecution, fines and loss of required government licenses, certifications and approvals, any of which could involve significant costs and could cause us to be unable to realize the expected benefits of these pharmacies' operations.

Further, under federal law, Section 503A of the FDCA seeks to limit the amount of compounded products that a pharmacy can dispense interstate. The interpretation and enforcement of this provision is dependent on the FDA entering into a standard Memorandum of Understanding ("MOU") with each state setting forth limits on shipments of interstate compounding. Previously, the draft MOU presented by the FDA in February 2015 intended to limit interstate shipments of compounded drug units to 30% of all compounded and non-compounded units dispensed or distributed by the pharmacy per month, the excess of which the FDA considered an "inordinate amount." The FDA stated in the guidance issued in February 2015 that it would not enforce interstate restrictions until after it published a final MOU and made it available to states for signature for some designated period of time. If the final MOU was drafted and released by the FDA and was not signed by a particular state, then interstate shipments of compounded preparations from a pharmacy located in that state would be limited to quantities not greater than 5% of total prescription orders dispensed or distributed by the pharmacy; however, we are not aware that the FDA currently enforces or has in the past enforced the 5% rule and, under current draft guidance, the FDA had historically stated that it would not enforce the 5% rule until a final MOU was made available to states for signature. The FDA originally proposed a 180-day period for states to agree to the final MOU after the final version was presented, which to date has not occurred, before it would begin to enforce the 5% rule. In January of 2018, the FDA released a "2018 Compounding Policy Priorities Plan" (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans to focus on in 2018 in connection with compounding regulations. One of the priorities outlined in the 2018 Compounding Plan addressed the current status of the MOU and the FDA's plan to release a revised MOU (the "Revised MOU"). Pursuant to the statements in the Compounding Plan, the Revised MOU would consider amounts shipped interstate by a compounder to be inordinate amounts if the "number of prescriptions of compounded drugs distributed interstate during any calendar month is greater than 50 percent." Importantly, instead of that number serving as a "hard limit, for state action," the 50% target would trigger certain additional reporting requirements. The Revised MOU will also provide states more time to report to the FDA, and flexibility on identifying when amounts are inordinate, considering the size and scope of compounding operations. Until the Revised MOU is issued and presented to states to consider, the extent of interstate dispensing restrictions imposed by Section 503A is unknown. However, if the final Revised MOU contains a 50% limit on interstate distribution, dependent on the additional reporting requirements to be outlined in the Revised MOU, our pharmacy operations could be materially limited.

***There are many competitive risks related to marketing and selling our proprietary formulations and operating our compounding pharmacy business.***

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and other compounding pharmacies. We are significantly smaller than some of our competitors. Currently we lack some of the financial and other resources needed to develop, produce, distribute and market our proprietary formulations at a level to capture a significant market share in these sectors. The drug products available through branded and generic drug companies with which our formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. Although we prepare our compounded formulations in accordance with the standards provided by the United States Pharmacopeia (“USP”) <795> and USP <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, which can in turn sell to and supply hospitals and retail pharmacies. Even if we are successful in registering certain of our facilities as outsourcing facilities, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors with FDA-approved drugs may not face.

***Our future success depends in large part on our ability to maintain a competitive position with respect to biotechnology and related pharmaceutical technologies.***

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies, could render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in their development, which may require us to raise additional funds that may or may not be available. The competitive environment requires an ongoing, extensive search for medical and technological innovations and the ability to develop and market these innovations effectively, and we may not be competitive with respect to these factors. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product. Although we believe we are positioned to compete favorably with respect to many of these factors, if our proprietary formulations are unable to compete with the products of our competitors, we may never gain market share or achieve sustained profitability.

***If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.***

The success of our business, including our proprietary formulations and pharmacy operations, is highly dependent upon medical and patient perceptions of us and the actual safety and quality of our products. We could be adversely affected if we, any other compounding pharmacies or our formulations and technologies are subject to negative publicity. We could also be adversely affected if any of our formulations or other products we sell, any similar products sold by other companies, or any products sold by other compounding pharmacies prove to be, or are asserted to be, harmful to patients. For instance, if any of the components of approved drugs or other ingredients used to produce our compounded formulations have quality or other problems that adversely affect the finished compounded preparations, our sales could be adversely affected. Because of our dependence upon medical and patient perceptions, adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products, any similar products sold by other companies, or any other compounded formulations could have a material adverse impact on our business.

To assure compliance with USP guidelines, we have a policy whereby 100% of all sterile compound batches produced by our ImprimisRx compounding pharmacies are tested prior to their delivery to patients and physicians both in-house and externally by an independent, FDA-registered laboratory that has represented to us that it operates in compliance with current good laboratory practices. However, we could still become subject to product recalls and termination or suspension of our state pharmacy licenses if we fail to fully implement this policy, if the laboratory testing does not identify all contaminated products, or if our products otherwise cause or appear to have caused injury or harm to patients. In addition, laboratory testing may produce false positives, which could harm our business and impact our pharmacy operations and licensure even if the impacted formulations are ultimately found to be sterile and no patients are harmed by them. If adverse events or deaths or a product recall, either voluntarily or as required by the FDA or a state board of pharmacy, were associated with one of our proprietary formulations or any compounds prepared by our ImprimisRx compounding pharmacies or any pharmacy partner, our reputation could suffer, physicians may be unwilling to prescribe our proprietary formulations or order any prescriptions from such pharmacies, we could become subject to product and professional liability lawsuits, and our state pharmacy licenses could be terminated or restricted. If any of these events were to occur, we may be subject to significant litigation or other costs and loss of revenue, and we may be unable to continue our pharmacy operations and further develop and commercialize our proprietary formulations.

***We carry product and professional liability insurance which may be inadequate.***

Although we have secured product and professional liability insurance for our pharmacy operations and the marketing and sale of our formulations, our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or at a level adequate to satisfy liabilities that may arise.

***Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement from third-party payors.***

Currently, our ImprimisRx compounding pharmacies operate on mostly a cash-pay basis and do not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors. As part of our Imprimis Cares initiative, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We plan to continue to devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations. We have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance for our formulations may be limited.

Additionally, we are making efforts to normalize the pricing for our currently available proprietary compounded formulations. Any efforts to attain optimized pricing for our Dropless Therapy or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

***We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.***

The estimates of our future operating and capital expenditures are based upon our current business plan, our current operations and our current expectations regarding the commercialization of our proprietary formulations. Our projections have varied significantly in the past as a result of changes to our business model and strategy, our termination of efforts to pursue FDA approval of a drug candidate in November 2013, our acquisitions of compounding facilities and various product and corporate development opportunities since 2014, and the expenses in developing our pharmacy facilities into outsourcing facilities and registering them as such with the FDA. We may not accurately estimate the potential revenues and expenses of our operations. If we are unable to correctly estimate the amount of cash necessary to fund our business, we could spend our available financial resources much faster than we expect. If we do not have sufficient funds to continue to operate and develop our business, we could be required to seek additional financing earlier than we expect, which may not be available when needed or at all, or be forced to delay, scale back or eliminate some or all of our proposed operations.

***If we do not successfully identify and acquire rights to potential formulations and successfully integrate them into our operations, our growth opportunities may be limited.***

We plan to pursue the development of new proprietary compounded formulations in the ophthalmology and/or other therapeutic areas, which may include continued activities to develop and commercialize current assets or, if and as opportunities arise, potential acquisitions of new intellectual property rights and assets. We also intend to seek opportunities to introduce new lower-cost compounded formulation alternatives to higher-priced FDA-approved drugs. However, we expect acquisitions of compounding pharmacies to provide us with only limited research and development support and access to additional novel compounded formulations. We have historically relied, and we expect to continue to rely, primarily upon third parties to provide us with additional development opportunities. We may seek to enter into acquisition agreements or licensing arrangements to obtain rights to develop new formulations in the future, but only if we are able to identify attractive formulations and negotiate acquisition or license agreements on terms acceptable to us, which we may not be able to do. Moreover, we have limited resources to acquire additional potential product development assets and integrate them into our business. Acquisition opportunities may involve competition among several potential purchasers, which could include large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. If we are unable to obtain rights to development opportunities from third parties and we are unable to rely upon our compounding pharmacies and current and future relationships with pharmacists, physicians and other inventors to provide us with additional development opportunities, our growth and prospects could be limited.

Our product development strategy is to focus on a select few therapeutic areas in which we believe there is broad market potential, large unmet needs and/or unique value to physicians and patients and to develop and offer formulations within these therapeutic areas that could afford us with gross margins. However, our expectations and assumptions about market potential and patient needs may prove to be wrong and we may invest capital and other resources on formulations that do not generate sufficient revenues for us to recoup our investment.

***We may be unable to successfully develop and commercialize our proprietary formulations or any other assets we may acquire.***

We have acquired assets related to compoundable formulations and we have entered into one license agreement for rights to commercialize a compounding formulation. We are currently pursuing development and commercialization opportunities with respect to certain of these formulations, and we are in the process of assessing certain of our other assets in order to determine whether to pursue their development or commercialization. In addition, we expect to consider the acquisition of additional intellectual property rights or other assets in the future. Once we determine to pursue a potential drug candidate, we develop a commercialization strategy for it, which may include marketing and selling the formulation in compounded form through compounding pharmacies or outsourcing facilities, or pursuing FDA approval of the drug candidate. We may incorrectly assess the risks and benefits of the commercialization options or we may not pursue a commercialization strategy that proves to be successful. If we are unable to successfully commercialize one or more of our proprietary formulations, our operating results would be adversely affected. Even if we are able to successfully sell one or more proprietary formulations, we may never recoup our investment in acquiring or developing the formulations. Our failure to identify and expend our resources on formulations and technologies with commercial potential and execute an effective commercialization strategy for each of our formulations would negatively impact the long-term profitability of our business.

***We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions.***

On July 19, 2017, we incurred \$16,000,000 of indebtedness under a loan agreement with SWK Funding, LLC and its partners (SWK) and concurrent with the funding, we utilized a portion of the SWK Loan funds as full payment to an affiliate of Life Sciences Alternative Funding, LLC (LSAF) to terminate all amounts due to LSAF in connection with the existing term loan and security agreements, as amended, originally entered into between the Company and LSAF on May 11, 2015 (the "LSAF Loan"), which loan had a principal balance of \$12,120,000 at the time of final payment.

Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional capital through equity sales or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, our SWK debt instrument contain various restrictive covenants, including, among others, our obligation to deliver to SWK certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without SWK's prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or repurchase any of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, SWK may be able to foreclose on our assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

***We may need additional capital in order to continue operating our business, and such additional funds may not be available when needed, on acceptable terms, or at all.***

We only recently started generating cash from operations, but we do not currently earn sufficient revenues to support our operations. We may need significant additional capital to execute our business plan and fund our proposed business operations. Additionally, our plans may change or the estimates of our operating expenses and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures, or we may experience growth more quickly or on a larger scale than we expect, any of which may result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

We have raised over \$59,000,000 in funds through equity and debt financings since January 2015. We may seek to obtain additional capital through equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or other financing transactions. If we issue additional equity or convertible debt securities to raise funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration and licensing arrangements or sales of assets, we may have to relinquish potentially valuable rights to our drug candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants included in our loan agreement with SWK. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

***We have in the past and may in the future participate in strategic transactions that could impact our liquidity, increase our expenses and distract our management.***

From time to time we consider engaging in strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies, and asset purchases. We may also consider a variety of different business arrangements in the future, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us or certain of our assets or aspects of our operations as an acquisition target. Any such transactions may require us to incur expenses specific to the transaction and not incident to our operations, may increase our near- and long-term expenditures, may pose significant integration challenges, may require us to hire or otherwise engage personnel with additional expertise, or may result in our selling or licensing of our assets or technologies under terms that may not prove profitable, any of which could harm our operations and financial results. Such transactions may also entail numerous other operational and financial risks, including, among others, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates, technologies or businesses.

As part of our efforts to complete any significant transaction, we would need to expend significant resources to conduct business, legal and financial due diligence, with the goal of identifying and evaluating material risks involved in the transaction. We may be unsuccessful in ascertaining or evaluating all the risks and, as a result, we may not realize the expected benefits of the transaction, whether due to unidentified risks, integration difficulties, regulatory setbacks or other events. We may incur material liabilities for the past activities of any businesses we partner with or acquire. If any of these events occur, we could be subject to significant costs and damage to our reputation, business, results of operations and financial condition.

***If we are unable to establish, train and maintain an effective sales and marketing infrastructure, we will not be able to commercialize our drug candidates successfully.***

We have started to build an internal sales and marketing infrastructure to implement our business plan by developing internal sales teams and education campaigns to market our proprietary formulations. We will need to expend significant resources to further establish and grow this internal infrastructure and properly train sales personnel with respect to regulatory compliance matters. We may also choose to engage or enter into other arrangements with third parties to provide sales and marketing services for us in place of or to supplement our internal commercialization infrastructure. We may not be able to secure sales personnel or relationships with third-party sales organizations that are adequate in number or expertise to successfully market and sell our proprietary formulations and pharmacy services. Further, any third-party organizations we may seek to partner with or engage may not be able to provide sales and marketing services in accordance with our expectations and standards, may be more expensive than we can afford or may not be available on otherwise acceptable terms or at all. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, through our own internal infrastructure or third-party services or other arrangements, we may be unable to sell our formulations or services or generate meaningful revenue.

***Our business and operations would suffer in the event of cybersecurity or other system failures.***

Despite the implementation of security measures, our internal computer systems and those of any third parties with which we partner are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any cybersecurity or system failure, accident or breach to date, if an event were to occur, it could result in a material disruption of our operations, substantial costs to rectify or correct the failure, if possible, and potentially violation of HIPAA and other privacy laws applicable to our operations. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or protected information, we could incur liability, further development of our proprietary formulations could be delayed, and our pharmacy operations could be disrupted, subject to restriction or forced to terminate their operations, any of which could severely harm our business and prospects.

***We depend upon consultants, outside contractors and other third-party service providers for key aspects of our business.***

We are substantially dependent on consultants and other outside contractors and service providers for key aspects of our business. For instance, we rely upon pharmacist, physician and research consultants and advisors to provide us with significant assistance in the evaluation of product development opportunities, and we have engaged or supported, and expect to continue to engage or support, consultants, advisors, clinical research organizations (CROs) and others to design, conduct, analyze and interpret the results of any clinical or non-clinical trials or other studies in connection with the research and development of our products. If any of our consultants or other service providers terminates its engagement with us, or if we are unable to engage highly qualified replacements as needed on commercially reasonable terms, we may be unable to successfully execute our business plan. We must effectively manage these third-party service providers to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, these third parties often engage in other business activities and may not devote sufficient time and attention to our activities and we may have only limited contractual rights in connection with the conduct of the activities we have engaged the service providers to perform. If we are unable to effectively manage our outsourced activities or if the quality, timeliness or accuracy of the services provided by third-party service providers is compromised for any reason, our development activities may be extended, delayed or terminated, and we may not be able to commercialize our formulations or advance our business.

## Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

***If we seek FDA approval to market and sell any of our proprietary formulations, such as with drug candidates being developed by Radley, Mayfield, Melt, Surface and Eton, we may be unable to demonstrate the necessary safety and efficacy to obtain such FDA approval.***

Historically, our business strategy was focused on developing and commercializing product opportunities as compounded formulations. In 2017 and in the future we, alone or with project partners, may seek FDA regulatory approval to market and sell one or more of our assets as a FDA-approved drug. Obtaining FDA approval to market and sell pharmaceutical products is costly, time consuming, uncertain and subject to unanticipated delays. The FDA or other regulatory agencies may not approve a drug candidate on a timely basis or at all. Before we obtain FDA approval for the sale of any potential drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that it is safe and effective for each intended use, which we may not be able to do. A failure to demonstrate safety and efficacy of a drug candidate to the FDA's satisfaction would result in our failure to obtain FDA approval. Moreover, even if the FDA were to grant regulatory approval of a drug candidate, the approval may be limited to specific therapeutic areas or limited as to its distribution, which could reduce revenue potential, and we will be subject to extensive and costly post-approval requirements and oversight with respect to commercialization of the drug candidate.

***Delays in the completion of, or the termination of, any clinical or non-clinical trials for any drug candidates for which we may seek FDA approval could adversely affect our business.***

Clinical trials are very expensive, time consuming, unpredictable and difficult to design and implement. The results of clinical trials may be unfavorable, they may continue for several years, and they may take significantly longer to complete and involve significantly more costs than expected. Delays in the commencement or completion of clinical testing could significantly affect product development costs and plans with respect to any drug candidate for which we seek FDA approval. The commencement and completion of clinical trials can be delayed and experience difficulties for a number of reasons, including delays and difficulties caused by circumstances over which we may have no control. For instance, approvals of the scope, design or trial site may not be obtained from the FDA and other required bodies in a timely manner or at all, agreements with acceptable terms may not be reached in a timely manner or at all with CROs to conduct the trials, a sufficient number of subjects may not be recruited and enrolled in the trials, and third-party manufacturers of the materials for use in the trials may encounter delays and problems in the manufacturing process, including failure to produce materials in sufficient quantities or of an acceptable quality to complete the trials. If we were to experience delays in the commencement or completion of, or if we were to terminate, any clinical or non-clinical trials we pursue in the future, the commercial prospects for the applicable drug candidates may be limited or eliminated, which may prevent us from recouping our investment in research and development efforts for the drug candidate and would have a material adverse effect on our business, results of operations, financial condition and prospects.

***We depend on the success of our drug candidates, and those we have royalty rights to, which have not yet demonstrated efficacy for their target or any other indications. If we are unable to generate revenues from our drug candidates, our ability to create stockholder value will be limited.***

Our drug candidates are in the early stages of clinical development. We do not generate revenues from any FDA approved drug products. We expect to submit an Investigational New Drug Application (“IND”) or foreign equivalent to the FDA or international regulatory authorities seeking approval to initiate our clinical trials in humans in the United States or other countries yet to be determined. We plan on submitting our clinical trial protocols and receive approvals from the FDA and international regulatory authorities before we can commence any clinical trials. We may not be successful in obtaining acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any drug candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our drug candidates, which may never occur.

***If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our drug candidate and our ability to generate revenue will be limited.***

We must successfully complete clinical trials for our drug candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our drug candidates’ safety and efficacy, before an NDA or Biologics License Application (“BLA”), or their foreign equivalents can be filed with the FDA or comparable foreign regulatory authorities for marketing approval of our drug candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our drug candidates is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of toxicology studies may not support the filing of an IND for our drug candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or “IRB”, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our drug candidates’ safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency (the “EMA”), or other regulatory agencies for marketing approval;
- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;

- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our drug candidates for the foregoing, or any other reasons, will prevent us from commercializing our drug candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our drug candidates.

Excluding any activities through our ownership interest in Eton, we have not submitted an NDA or received regulatory approval to market our drug candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or “CROs”, with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a drug candidate’s safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the drug candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a drug candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our drug candidates in any indication will prevent us from commercializing the drug candidate, and our ability to generate revenue will be materially impaired.

***If we fail to successfully commercialize any of our drug candidates, we may need to acquire additional drug candidates and our business will be adversely affected.***

We have never commercialized any drug candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond our drug candidates. We cannot be certain that any of our drug candidates will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize any of our drug candidates for their targeted indications, whether as stand-alone therapies or in combination with other therapeutic agents, our business would be adversely affected.

***Even if we receive regulatory approval for any of our drug candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.***

If approved for marketing, the commercial success of our drug candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates, and the target patient population to try new therapies;
- efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our drug candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our drug candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, "REMS", to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

***Even if we obtain marketing approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.***

Even if we obtain regulatory approval for any of our drug candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or “cGCPs”, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product’s approved labeling. If we receive marketing approval for our drug candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

***Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/ or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

***Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or "MMA", changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Efforts to date have generally been unsuccessful. If the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal or modification in the implementation of the Health Care Reform Law on us at this time.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

***Our drug candidates may face competition sooner than expected.***

Our success will depend in part on our ability to obtain and maintain patent protection for our certain of our drug candidates and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against compounding pharmacies, outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own.

We also intend to seek data exclusivity or market exclusivity for our drug candidates provided under the FDCA, and similar laws in other countries. The FDCA provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Even if our drug candidates are considered to be reference products eligible for 3 years of exclusivity under the FDCA, another company could market competing products if the FDA approves a full NDA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the FDCA could result in a shorter exclusivity period for our drug candidates, which would have a material adverse effect on our business.

***If we market any of our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.***

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

***We will be completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.***

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, ("API"), in our drug candidates for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate any of our drug candidates as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our drug candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our drug candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our drug candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply any of our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our drug candidates if we decided to transfer the manufacture of any of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our drug candidates over time. If the commercial-scale manufacturing costs of any of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

***We expect to rely on third parties to conduct clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our drug candidates and our business would be substantially harmed.***

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for our drug candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our drug candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for any of our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.***

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of drug candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for any of our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our drug candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our drug candidates could be significantly reduced.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing of drug candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our drug candidates will achieve positive results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our drug candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

***Even though we may apply for orphan drug designation for a drug candidate, we may not be able to obtain orphan drug marketing exclusivity.***

There is no guarantee that the FDA, EMA or their foreign equivalents will grant any future application for orphan drug designation for any of our drug candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to \$400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates in the indications for which we think they might qualify, if we elect to seek such applications.

***Although we may pursue expedited regulatory approval pathways for a drug candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.***

Although we believe there may be an opportunity to accelerate the development of certain of our drug candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review, we cannot be assured that any of our drug candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for breakthrough therapy designation or any other expedited program for our drug candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a breakthrough therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such drug candidate.

***If we are unable to protect our proprietary rights, we may not be able to prevent others from using our intellectual property, which may reduce the competitiveness and value of the related assets.***

Our success will depend in part on our ability to obtain and maintain patent protection for our formulations and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. The primary means by which we will be able to protect our formulations and technologies from unauthorized use by third parties is to obtain valid and enforceable patents that cover them. As of February 28, 2019, we owned and/or licensed nine U.S. issued patents, two international issued patents, and 32 U.S. patent applications, including 29 utility (including continuation, continuation-in-part and divisional) and three provisional patent applications, and we owned seven international patent applications filed under the Patent Cooperation Treaty and 42 foreign patent applications. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against other compounding pharmacies and outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own. We have made, and expect to continue to make, significant investments in certain of our proprietary formulations prior to the grant of any patents covering these formulations, and we may not receive a sufficient return on these investments if patent coverage or other appropriate intellectual property protection is not obtained and their competitiveness and value decreases.

The patent and intellectual property positions of pharmacies and pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have developed or obtained or will in the future develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we have developed or may in the future develop or to which we have acquired or may in the future acquire development rights. In addition, we cannot be certain that patents issued to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our formulations, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, collaborators and others, including certain service providers. We also have invention or patent assignment agreements with our current employees and certain consultants. Nonetheless, our employees and consultants may breach these agreements, and we may not have adequate remedies for the breach. Our trade secrets may otherwise become known or be independently discovered by competitors or could be developed by a person not bound by an invention assignment agreement with us, in which case we may have no rights to use the applicable invention.

***We may face additional competition outside of the U.S. as a result of a lack of patent coverage in some territories and differences in patent prosecution and enforcement laws in foreign countries.***

Filing, prosecuting, defending and enforcing patents on our proprietary formulations throughout the world is extremely expensive. We do not currently have patent protection outside of the U.S. that covers any of our proprietary formulations or other assets that we are currently pursuing. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection.

Even if the international patent applications we have filed or may in the future file are issued or approved, it is likely that the scope of protection provided by such patents would be different from, and possibly less than, the scope provided by corresponding U.S. patents. As a result, patent rights we are able to obtain may not be sufficient to prevent generic competition. Further, the extent of our international market opportunity may be dependent upon the enforcement of patent rights in various other countries. A number of countries in which we could file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which would make it difficult for us to stop a third party from infringing any of our intellectual property rights. Moreover, attempting to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

***Our proprietary formulations and technologies could potentially conflict with the rights of others.***

The preparation or sale of our proprietary formulations and use of our technologies may infringe on the patent or other intellectual property rights of others. If our products infringe or conflict with the patent or other intellectual property rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin our manufacturing and marketing of our affected products. Patent litigation is costly and time consuming and may divert management's attention and our resources. We may not have sufficient resources to bring any actions to a successful conclusion. If we are not successful in defending against these legal actions should they arise, we may be subject to monetary liability or be forced to alter our products, cease some or all of our operations relating to the affected products, or seek to obtain a license in order to continue manufacturing and marketing the affected products, which may not be available on acceptable terms or at all.

***We are dependent on our Chief Executive Officer, Mark L. Baum, and other key persons for the continued growth and development of our Company.***

Our Chief Executive Officer, Mark L. Baum, has played a primary role in creating and developing our current business model. Further, Mr. Baum has played a primary role in securing much of our material intellectual property rights and related assets, as well as the means to make and distribute our current products. We are highly dependent on Mr. Baum for the implementation of our business plan and the future development of our assets and our business, and the loss of Mr. Baum's services and leadership would likely materially adversely impact our Company. We presently maintain key man insurance for Mr. Baum. In addition, our loan agreement, identifies other key persons including, but not limited to, our Chief Financial Officer, Andrew R. Boll and our President of ImprimisRx, John P. Saharek.

***If we are unable to attract and retain key personnel and consultants, we may be unable to maintain or expand our business.***

We have been focusing on building our management, pharmacy, research and development, sales and marketing and other personnel to pursue our current business model. To achieve our planned growth, we may have significant difficulty attracting and retaining necessary employees. Because of the specialized nature of our business, the ability to develop products and to compete will remain highly dependent upon our ability to attract and retain qualified pharmacy, scientific, technical and commercial employees and consultants. There is intense competition to hire qualified personnel in our industry, and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business. The loss of key employees or consultants or the failure to recruit or engage new employees and consultants could have a material adverse effect on our business.

#### **Risks Related to Our Common Stock**

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results, which could cause our stock price to fall.***

Effective internal controls are necessary for us to provide reliable financial results. If we cannot provide reliable financial results, our consolidated financial statements could be misstated, our reputation may be harmed and the trading price of our common stock could decline. As we discussed in Item 9A of this Annual Report, our management concluded that our internal controls over financial reporting were effective as of December 31, 2018. However, our controls over financial processes and reporting may not continue to be effective or we may identify material weaknesses or significant deficiencies in our internal controls in the future. Any failure to remediate any future material weaknesses or successfully implement required new or improved controls, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements or other public disclosures. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

***A consistently active trading market for shares of our common stock may not be sustained.***

Historically, trading in our common stock has been sporadic and volatile and our common stock has been "thinly-traded." There have been, and may in the future be, extended periods when trading activity in our shares is minimal, as compared to a seasoned issuer with a large and steady volume of trading activity. The market for our common stock is also characterized by significant price volatility compared to seasoned issuers, and we expect that such volatility may continue. As a result, the trading of relatively small quantities of shares may disproportionately influence the market price of our common stock. A consistently active and liquid trading market in our securities may never develop or be sustained.

***Our stock price may be volatile.***

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following: our ability to execute our business plan; operating results that fall below expectations; industry or regulatory developments; investor perception of our industry or our prospects; economic and other external factors; and the other risk factors discussed in this "Risk Factors" section.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

***We have the right to issue shares of preferred stock without obtaining stockholder approval. If we were to issue preferred stock, it may have rights, preferences and privileges superior to those of our common stock.***

We are authorized to issue 5,000,000 shares of “blank check” preferred stock, with such rights, preferences and privileges as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue preferred stock at any time in one or more series and to fix the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights and other rights, preferences and privileges for any series of our preferred stock that may be issued. The issuance of shares of preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could reduce the voting rights and powers of our common stockholders and the portion of our assets allocated for distribution to our common stockholders in a liquidation event, and could also result in dilution to the book value per share of our common stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of our Company.

***We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on an investment will be limited to any appreciation in the value of our common stock.***

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. Any payment of dividends on our common stock would depend on contractual restrictions, such as those contained in our SWK loan agreement and convertible note, as well as our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

***Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

The sale of substantial amounts of our common stock in the public market, or the perception that sales could occur, may cause the market price of our common stock to fall. Sales could occur upon the expiration of any statutory holding period, such as under Rule 144 under the Securities Act of 1933, as amended, applicable to outstanding shares, upon expiration of any lock-up periods applicable to outstanding shares, upon our issuance of shares upon the exercise of outstanding options or warrants, or upon our issuance of shares pursuant offerings of our equity securities. The availability for sale of a substantial number of shares of our common stock, whether or not sales have occurred or are occurring, also could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future when needed, on acceptable terms or at all.

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

None.

## **Item 3. Defaults Upon Senior Securities**

Not applicable.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## Item 5. Other Information

On May 6, 2019, we entered into an Asset Purchase Agreement with Eton (the “CT APA”) to re-acquire assets related to our synthetic corticotropin formulation from Eton (CT-100). The CT APA requires royalty on net sales of 3%, subject to adjustments, and milestone payments that allow for three separate payments of \$100,000, \$200,000 and \$700,000 to Eton (\$1,000,000, in aggregate) upon submission of an investigational new drug application, regulatory approval and at the point when cumulative net sales of CT-100 exceed \$50,000,000, respectively.

## Item 6. Exhibits

<b>Exhibit Number</b>	<b>Description</b>
10.1	<a href="#">Asset Purchase Agreement dated December 11, 2018 between Harrow Health, Inc. (fka Imprimis Pharmaceuticals, Inc.) and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on February 5, 2019).</a>
10.2*	<a href="#">Asset Purchase Agreement dated February 1, 2019 between Harrow Health, Inc. and Mayfield Pharmaceuticals, Inc.</a>
10.3*	<a href="#">Asset Purchase Agreement dated February 1, 2019 between Harrow Health, Inc. and Elle Pharmaceuticals, Inc.</a>
31.1*	<a href="#">Certification of Mark L. Baum, principal executive officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Andrew R. Boll, principal financial and accounting officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.</a>
32.1**	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L. Baum, principal executive officer, and Andrew R. Boll, principal financial and accounting officer.</a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase

\* Filed herewith.

\*\* Furnished herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Harrow Health, Inc.**

Dated: May 9, 2019

By: /s/ Mark L. Baum

Mark L. Baum  
Chief Executive Officer and Director  
(Principal Executive Officer)

By: /s/ Andrew R. Boll

Andrew R. Boll  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



## ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this “Agreement”) dated as of February 1, 2019 (the “Effective Date”), is entered into between HARROW HEALTH, INC., a Delaware corporation (“Harrow”), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130, and MAYFIELD PHARMACEUTICALS, INC., a Nevada corporation (“Mayfield”), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130. The parties hereby agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the respective meanings set forth below, and grammatical variations of such terms shall have corresponding meanings:

1.1 “Affiliate” means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever. Notwithstanding the foregoing, for purposes of this Agreement, neither Harrow nor Mayfield shall be Affiliates of the other or the other’s Affiliates.

1.2 “Assets” means, collectively, (a) all Technology, (b) the Assigned Patent Rights, (c) the Assigned Know-How Rights, and (d) all compositions, formulations, samples, data and information specific to the Technology owned by Harrow as of the Effective Date; in each case, acquired from Elle by Harrow pursuant to the Elle APA.

1.3 “Assigned Know-How Rights” means all trade secret and other know-how rights acquired from Elle by Harrow pursuant to the Elle APA.

1.4 “Assigned Patent Rights” means, collectively, (a) all patents and patent applications (including provisional patent applications) acquired from Elle by Harrow pursuant to the Elle APA, including those listed on Schedule A, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, *inter partes* reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

1.5 “Confidential Information” means all information and data that (a) is provided by one party to the other party under this Agreement, and (b) if disclosed in writing or other tangible medium is marked or identified as confidential at the time of disclosure to the recipient, is acknowledged at the time of disclosure to be confidential, or otherwise should reasonably be deemed to be confidential, except that the Assets shall be the Confidential Information of both parties. Notwithstanding the foregoing, Confidential Information of a party shall not include that portion of such information and data which, and only to the extent, the recipient can establish by written documentation: (i) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing party, (ii) is disclosed to the recipient free of confidentiality obligations by a third person who has the right to make such disclosure, (iii) is or becomes part of the public domain through no fault of the recipient, or (iv) the recipient can reasonably establish is independently developed by persons on behalf of recipient without access to or use of the information disclosed by the disclosing party.

1.6 “Dyspareunia Product” means any product, in any gel-based form or formulation, containing lidocaine as an active pharmaceutical ingredient with a concentration in the range of 3.18% to 4.40% for the treatment of dyspareunia.

1.7 “Elle” means Elle Pharmaceutical, LLC.

1.8 “Elle APA” means the Asset Purchase Agreement entered into between Elle and Harrow on or around the Effective Date, as amended or restated from time to time.

1.9 “FDA” means the United States Food and Drug Administration, or any successor entity thereto.

1.10 “Harrow Field” means drug products compounded or manufactured in compounding pharmacies or outsourcing facilities as defined and described in the Federal Food, Drug & Cosmetic Act (21 U.S.C §353a and 21 U.S.C. §353b).

1.11 “Licensee” means a Third Party to whom Mayfield or its Affiliate has granted a license, immunity or other right under the Assigned Patent Rights to offer to sell, sell or otherwise commercialize one or more Dyspareunia Products, provided such license has not expired or been terminated.

1.12 “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group of any of the foregoing.

1.13 “Product Supported Patent Rights” means, collectively, (a) all patent applications hereafter filed anywhere in the world, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, *inter partes* reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof; in each case that use or are supported by data or information derived from the development, manufacture or use of a Dyspareunia Product or otherwise from the exploitation of the Assets; provided, however, that Product Supported Patent Rights shall exclude the Assigned Patent Rights.

1.14 “Technology” means, collectively, (a) Dyspareunia Product, (b) all compositions, components and formulations thereof, and (c) any and all methods of manufacture and uses of the foregoing.

1.15 “Third Party” means any Person other than Harrow, Mayfield or their respective Affiliates.

## 2. Purchase and Sale of the Assets.

2.1 Assets. Subject to the terms and conditions of this Agreement, Mayfield hereby purchases from Harrow, and Harrow hereby sells, conveys, transfers and assigns to Mayfield, on the Effective Date, all of Harrow’ right, title and interest in and to the Assets. To the extent necessary to comply with applicable privacy laws, Harrow shall have the right to redact patient identifying information from any data or information transferred to Mayfield.

2.2 No Assumption of Liabilities. Mayfield shall not be obligated to assume or perform and is not assuming or performing any liabilities or obligations of Harrow which relate to Harrow’ ownership of the Assets prior to the Effective Date or otherwise, whether known or unknown, fixed or contingent, certain or uncertain, and regardless of when they are or were asserted, and Harrow shall remain responsible for such liabilities.

2.3 Transfer Documents. The sale, conveyance, transfer and assignment of the Assets may be further evidenced by the due execution and delivery by the parties of any additional bills of sale, assignment or other title transfer documents and instruments as reasonably requested by Mayfield evidencing the sale, conveyance, transfer and assignment of the Assets in accordance with this Agreement.

## 3. License Grants.

### 3.1 Grantback License.

3.1.1 Subject to the terms and conditions of this Agreement, Mayfield hereby grants to Harrow an exclusive (including with respect to Mayfield), irrevocable, perpetual, fully paid-up, royalty-free, non-transferable (except in connection with a permitted assignment of this Agreement), worldwide license under the Assigned Patent Rights, the Product Supported Patent Rights, and the Assigned Know-How Rights for all purposes in the Harrow Field.

3.1.2 Harrow shall have the right to grant sublicenses, through multiple tiers, to Third Parties and Affiliates.

3.2 No Implied Licenses. Only licenses and rights expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel, or otherwise.

4. Representations and Warranties.

4.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as follows:

4.1.1 Organization. Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

4.1.2 Authorization and Enforcement of Obligations. Such party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

4.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such party in connection with this Agreement have been obtained.

4.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and (b) do not conflict with, or constitute a default under, any contractual obligation of such party.

4.2 DISCLAIMER OF WARRANTIES. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN SECTION 4.1, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE ASSETS OR ANY OTHER MATTER, INCLUDING WITHOUT LIMITATION, ANY REPRESENTATION OR WARRANTY REGARDING VALIDITY, ENFORCEABILITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT. THE ASSETS ARE PROVIDED "AS IS."

5. Financial Terms. As a condition precedent to the effect of this Agreement, Mayfield shall enter into a written agreement with Elle, pursuant to which Mayfield shall pay certain amounts to Elle on terms and conditions to be mutually agreed by Mayfield and Elle.

6. Post-Effective Date Covenants.

6.1 Mayfield Covenants.

6.1.1 Mayfield shall use commercially reasonable efforts (whether alone or with or through its Licensees or its or their respective Affiliates) to research, develop and commercialize Dyspareunia Product.

6.1.2 Mayfield shall complete the closing of equity financing(s) of Mayfield with net proceeds received by Mayfield of not less than ten million dollars (\$10,000,000) by June 1, 2020.

6.1.3 Mayfield shall control, at its sole expense, the preparation, filing, prosecution, maintenance and enforcement of the Assigned Patent Rights consistent with prudent business practices, and shall consider in good faith the interests of Harrow.

6.1.4 Mayfield shall enter into a stock issuance agreement with Elle dated as of the Effective Date and shall issue to Elle certain shares of common stock of Mayfield to Elle pursuant to, and on the terms and conditions of, such stock issuance agreement.

## 6.2 Harrow Covenants.

6.2.1 Within thirty (30) days after the Effective Date, Harrow shall transfer to Mayfield all tangible embodiments of the Technology in the possession and control of Harrow.

6.2.2 Harrow shall provide cooperation reasonably requested by Mayfield in connection with Mayfield's efforts to establish, perfect, defend, or enforce its rights in or to the Assets (including without limitation the Assigned Patent Rights). Such cooperation shall include, without limitation, (a) executing such further assignments, transfers, licenses, releases and consents, and (b) providing such data and information, consulting with Mayfield and executing and delivering all such further documents and instruments, in each case as reasonably requested by Mayfield regarding the Assets (including without limitation the Assigned Patent Rights).

6.2.3 If a New Drug Application for a Dyspareunia Product is filed by or on behalf of Mayfield and Mayfield (or its designee) receives all applicable marketing and pricing approvals from the FDA regarding such New Drug Application, then, commencing thirty (30) days after receipt by Harrow of Mayfield's express written request, Harrow shall cease compounding pharmaceutical products for treatment of dyspareunia that contain the same active ingredient as contained in such Dyspareunia Product in concentrations between fifty percent (50%) and two hundred percent (200%) of the concentration of such active ingredient in such Dyspareunia Product (or, if there is more than one active ingredient contained in such Dyspareunia Product, then the same combination of active ingredients in concentrations between fifty percent (50%) and two hundred percent (200%) of the concentrations as contained in such Dyspareunia Product) until such time as Mayfield, its Licensees and its or their respective Affiliates (or their successors) cease for at least twelve (12) months bona fide development or commercialization of such Dyspareunia Product. Mayfield promptly shall notify Harrow in writing of any such cessation.

## 7. Indemnification.

7.1 Indemnification by Harrow. Subject to the provisions of this Section 7, Harrow shall indemnify, defend and hold harmless Mayfield, its officers, directors, affiliates, agents, stockholders and representatives (collectively, the "Mayfield Indemnitees"), from and against any and all losses, liabilities, damages and expenses (including without limitation reasonable attorneys' fees and costs) incurred as a result of any claim, demand, action or proceeding by any Third Party (collectively, "Losses") incurred or suffered by an Mayfield Indemnitee to the extent arising out of:

7.1.1 any breach of the representations and warranties of Harrow set forth in this Agreement;

7.1.2 any breach of any covenant or agreement of Harrow set forth in this Agreement or in any certificate, instrument, or other document delivered pursuant to this Agreement; and

7.1.3 the ownership or exploitation of the Assets prior to the Effective Date.

7.2 Indemnification by Mayfield. Subject to the provisions of this Section 7, Mayfield shall indemnify and hold harmless Harrow, its officers, directors, affiliates, agents, stockholders and representatives (collectively, the "Harrow Indemnitees"), from and against any and all Losses incurred or suffered by an Harrow Indemnitee to the extent arising out of:

7.2.1 any breach of the representations and warranties of Mayfield set forth in this Agreement;

7.2.2 any breach of any covenant or agreement of Mayfield set forth in this Agreement or in any certificate, instrument, or other document delivered pursuant to this Agreement;

7.2.3 the ownership or exploitation of the Assets after the Effective Date or the manufacture, use, sale or other exploitation of any Dyspareunia Product solely by Mayfield, its Licensees or their respective Affiliates or the use of any Dyspareunia Product by their customers.

7.3 Procedure. A party seeking indemnification (the "Indemnitee") shall promptly notify the other party (the "Indemnifying Party") in writing of a claim or suit; provided that an Indemnitee's failure to give such notice or delay in giving such notice shall not affect such Indemnitee's right to indemnification under this Section 7 except to the extent that the Indemnifying Party has been prejudiced by such failure or delay. The Indemnifying Party shall have the right to control the defense of all indemnification claims hereunder. The Indemnitee shall have the right to participate at its own expense in the claim or suit with counsel of its own choosing. The Indemnifying Party shall consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested, at the Indemnifying Party's sole cost and expense. The Indemnifying Party shall not settle any claim or suit without the Indemnitee's prior written consent, which consent shall not be unreasonably withheld.

## 8. Confidentiality.

8.1 Confidential Information. During the term of this Agreement, and for a period of five (5) years following the expiration or earlier termination hereof, except as otherwise provided in this Section 8, each party shall maintain in confidence the Confidential Information of the other party except as expressly permitted herein, and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, employees, (sub)licensees and contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure by a party is authorized by this Agreement, prior to disclosure, such party shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement.

8.2 Terms of this Agreement. Neither party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other party; provided, however, that a party may disclose the terms or conditions of this Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, and (b) to a Third Party in in confidence in connection with (i) an equity investment in such party, (ii) a merger, consolidation or similar transaction by such party, (iii) a permitted (sub)license under this Agreement, or (iv) the sale of all or substantially all of the assets of such party. Notwithstanding the foregoing, prior to execution of this Agreement, the parties have agreed upon the substance of information that can be used to describe the terms of this transaction, and each party may disclose such information, as modified by mutual agreement from time to time, without the other party's consent.

8.3 Permitted Disclosures. The confidentiality obligations contained in this Section 8 shall not apply to the extent that a party is required (a) in the reasonable opinion of such party's legal counsel, to disclose information by applicable law, regulation, rule (including rule of a stock exchange or automated quotation system), order of a governmental agency or a court of competent jurisdiction or legal process, including tax authorities, or (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that, to the extent practicable, such party shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment. Notwithstanding anything to the contrary herein, either party may disclose the terms and conditions of this Agreement to any Person with whom such party has, or is proposing to enter into, a business relationship, as long as such Person has entered into a confidentiality agreement with such party.

8.4 Injunctive Relief. Each party acknowledges that it will be impossible to measure in money the damage to the other party if such party fails to comply with the obligations imposed by this Section 8, and that, in the event of any such failure, the other party may not have an adequate remedy at law or in damages. Accordingly, each party agrees that injunctive relief or other equitable remedy, in addition to remedies at law or damages, is an appropriate remedy for any such failure and shall not oppose the granting of such relief on the basis that the disclosing party has an adequate remedy at law. Each party agrees that it shall not seek, and agrees to waive any requirement for, the securing or posting of a bond in connection with the other party seeking or obtaining such equitable relief.

## 9. Term and Termination.

9.1 Term. The term of this Agreement shall continue until expiration of all payment obligations hereunder, unless earlier terminated as set forth below.

## 9.2 Termination.

9.2.1 If Mayfield, its Licensees, or their respective Affiliates (a) fail to use commercially reasonable efforts to develop and commercialize a Dyspareunia Product within the United States, or thereafter to use reasonable efforts to actively promote, market and sell such Dyspareunia Product within the United States, or (b) fail to file an Investigational New Drug Application in the United States for a Dyspareunia Product before the third (3rd) anniversary of the Effective Date, then Mayfield shall provide written notice thereof to Harrow and, unless the parties otherwise mutually agree in writing, Harrow shall have the right to terminate the Agreement effective immediately upon written notice of termination to Mayfield.

9.2.2 If Mayfield fails to receive net proceeds of the sale of its equity securities to Third Parties of at least ten million dollars (\$10,000,000) in cash, whether individually or in the aggregate, by June 1, 2020, then (a) Mayfield promptly shall provide written notice thereof to Harrow and (b) Harrow shall have the right to terminate this Agreement immediately by providing Mayfield with written notice of termination within thirty (30) days after Mayfield's notice described in clause (a).

9.2.3 In the event of the termination of this Agreement in accordance with this Section 9.2, Mayfield promptly shall re-assign the Assets to Harrow or its designee. Mayfield shall execute, acknowledge and deliver such further documents and instruments and perform all such other acts as may be reasonably necessary or appropriate in order to effectuate the foregoing.

9.3 Survival. Expiration or termination of this Agreement shall be without prejudice to any rights which shall have accrued to the benefit of any party prior to such expiration. Without limiting the foregoing, Sections 3, 4.2, 5, 7, 8, 9.2.3, 9.3, and 10 shall survive any expiration or termination of this Agreement.

## 10. Miscellaneous.

10.1 Further Actions. Each party shall execute, acknowledge and deliver such further documents and instruments and to perform all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

10.2 LIMITATION OF LIABILITY. IN NO EVENT SHALL A PARTY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.2 SHALL LIMIT OR RESTRICT THE RIGHTS OR LIABILITIES OF EITHER PARTY UNDER SECTIONS 7 AND 8.

10.3 Residuals. Notwithstanding anything to the contrary in this Agreement, Harrow shall have the right to use any general knowledge, skills and experience and any information retained in the unaided memory of an individual employed or otherwise engaged by Harrow.

10.4 Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that a party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 10.4 shall be void.

10.5 Severability. Any provision of this Agreement which is illegal, invalid or unenforceable shall be ineffective to the extent of such illegality, invalidity or unenforceability, without affecting in any way the remaining provisions hereof.

10.6 Governing Law; Exclusive Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to the conflicts of law principles thereof. Each of the parties hereto irrevocably consents to the exclusive jurisdiction and venue of any federal court located in the Southern District of the State of California or state court in San Diego, California having jurisdiction, in connection with any matter based upon or arising out of this Agreement or the matters contemplated herein, agrees that process may be served upon them in any manner authorized by laws of the State of California for such persons and waives and covenants not to assert or plead any objection which they might otherwise have to such jurisdiction, venue and such process.

10.7 Entire Agreement; Amendment. This Agreement, together with the Schedules hereto, and each additional document, instrument or other agreement to be executed and delivered pursuant hereto constitute all of the agreements of the parties with respect to, and supersede all prior agreements and understandings relating to the subject matter of, this Agreement or the transactions contemplated by this Agreement. This Agreement may not be modified or amended except by a written instrument specifically referring to this Agreement signed by the parties hereto.

10.8 Waiver. No waiver by one party of the other party's obligations, or of any breach or default hereunder by any other party, shall be valid or effective, unless such waiver is set forth in writing and is signed by the party giving such waiver; and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such other party.

10.9 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by a party to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to Harrow: Harrow Health, Inc.  
12264 El Camino Real, Suite 350  
San Diego, California 92130  
Attention: Chief Executive Officer

If to Mayfield: Mayfield Pharmaceuticals, Inc.  
12264 El Camino Real, Suite 350  
San Diego, California 92130  
Attention: Executive Director

10.10 Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, each party has caused a duly authorized representative to execute and deliver this Asset Purchase Agreement as of the Effective Date.

HARROW HEALTH, INC.

By: /s/ Mark Baum

Name: Mark Baum

Title: Chief Executive Officer

MAYFIELD PHARMACEUTICALS, INC.

By: /s/ Andrew Boll

Name: Andrew Boll

Title: Executive Director

[Signature Page to Asset Purchase Agreement]

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SCHEDULE A

Assigned Patent Rights

A-1

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## ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this "Agreement") dated as of February 1, 2019 (the "Effective Date"), is entered into between ELLE PHARMACEUTICAL, LLC, a Delaware limited liability company ("Elle"), with a place of business at, and HARROW HEALTH, INC., a Delaware corporation ("Harrow"), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130. The parties hereby agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the respective meanings set forth below, and grammatical variations of such terms shall have corresponding meanings:

1.1 "Affiliate" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever. Notwithstanding the foregoing, for purposes of this Agreement, neither Harrow nor Mayfield Pharmaceuticals, Inc. ("Mayfield") shall be Affiliates of the other or the other's Affiliates.

1.2 "Assets" means, collectively, (a) the Technology; (b) all discoveries, inventions, technology, compositions, formulations, samples, components, processes, standards, methods, inventories, supplies, equipment, procedures and techniques relating thereto; (c) all formulae, data, information, results of experimentation and testing, and other know-how, whether or not patentable or copyrightable, relating thereto; (d) all product registrations and applications therefor relating thereto; and (e) all intellectual property rights and other assets relating thereto (including without limitation the Assigned Patent Rights and Assigned Know-How Rights).

1.3 "Assigned Know-How Rights" means all trade secret and other know-how rights related to the Technology or which are necessary or useful to make, use, develop, sell or seek regulatory approval to market a composition, or to practice any method or process, at any time claimed or disclosed in any issued patent or pending patent application within the Assigned Patent Rights, whether existing as of the Effective or hereinafter developed or acquired.

1.4 "Assigned Patent Rights" means, collectively, (a) all patents and patent applications (including provisional patent applications) in any jurisdiction that claim the Technology (whether existing before or after the Effective Date), including those listed on Schedule 1 to Exhibit A, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, *inter partes* reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

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1.5 “Contract” or “Contracts” means any mortgage, indenture, lease, contract, covenant, arrangement, agreement, instrument, commitment, purchase order or license.

1.6 “Dyspareunia Product” means any product, in any gel-based form or formulation, containing lidocaine as an active pharmaceutical ingredient with a concentration in the range of 3.18% - 4.40% for the treatment of dyspareunia.

1.7 “Encumbrance” or “Encumbrances” means any encumbrance, lien, charge, hypothecation, pledge, mortgage, adverse claim, option, preemptive right, or other security interest of any nature, or any Contract to create any of the foregoing entered into by Elle on or before the Effective Date.

1.8 “First Commercial Sale” means, with respect to any Product, the first sale of such Product by Harrow, its Licensees, or its or their respective Affiliates after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing health authority.

1.9 “GAAP” means United States generally accepted accounting principles.

1.10 “Improvement Patent Rights” means, collectively, (a) all patent applications hereafter filed anywhere in the world, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, *inter partes* reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof; in each case (i) that have an earliest priority date that is after the Effective Date and before the effective date of termination pursuant to Section 9.2, (ii) that claim the Dyspareunia Product or the manufacture or use thereof, and (iii) in which and only to the extent that Harrow has a licensable interest exercisable without violating the terms of any agreement or other arrangement with any Third Party or incurring any additional royalty, fee or other charge; provided, however, that Improvement Patent Rights shall exclude the Assigned Patent Rights.

1.11 “Knowledge of Elle” or “Elle’s Knowledge” means the actual knowledge of any director, officer, member or employee of Elle and the Knowledge such individuals would reasonably be expected to obtain in the course of diligently performing his or her duties for Elle and/or making a reasonable inquiry into the matters contemplated by this Agreement.

1.12 “Licensee” means a Third Party to whom Harrow or its Affiliate has granted a license, immunity or other right under the Assigned Patent Rights to offer to sell, sell or otherwise commercialize one or more Products, provided such license has not expired or been terminated.

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1.13 “Net Sales” means, with respect to any Product, the gross sales price of such Product invoiced by Harrow, its Licensees, and its and their respective Affiliates to customers who are not Affiliates (or are Affiliates but are the end users of such Product), less: (a) credits, allowances, discounts and rebates to, and chargebacks from the account of, such customers; (b) freight and insurance costs in transporting Product; (c) cash, quantity and trade discounts, rebates and other price reductions for Product; (d) sales, use, value-added and other direct taxes; (e) customs duties, tariffs, surcharges and other governmental charges incurred in exporting or importing Product; (f) an allowance for uncollectible or bad debts determined in accordance with GAAP not to exceed three percent (3%) of Net Sales of such Product for the applicable quarterly reporting period before giving effect to this subsection (f); and (g) the fully-burdened cost of goods sold determined in accordance with GAAP.

1.14 “Other Product” means any product in any gel-based form or formulation, the manufacture, use, sale, offer for sale, lease or importation of which would constitute an infringement, an inducement to infringe or contributory infringement of any Valid Claim (if such Valid Claim were in an issued patent not owned by or licensed to Harrow) but is not a Dyspareunia Product.

1.15 “Payment Period” means, on a Product-by-Product and country-by-country basis, the period of time beginning on the date of the First Commercial Sale of such Product in such country and continuing during the term for which a Valid Claim (if such Valid Claim were in an issued patent) in such country remains in effect and would be infringed (if such Valid Claim were in an issued patent not owned by or licensed to Harrow) by the manufacture, use, offer for sale, sale or import of such Product in such country.

1.16 “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group of any of the foregoing.

1.17 “Product” means a Dyspareunia Product or an Other Product.

1.18 “Tax” or “Taxes” means any and all federal, state, local and foreign taxes, assessments and other governmental charges, duties, impositions and liabilities, including taxes based upon or measured by gross receipts, income, profits, sales, use and occupation, and value added, ad valorem, transfer, franchise, withholding, payroll, recapture, employment, excise and property taxes as well as public imposts, fees and social security charges (including but not limited to health, unemployment and pension insurance), together with all interest, penalties and additions imposed with respect to such amounts and any obligation under any agreement or arrangement with any other Person with respect to such amounts and including any liability for taxes of a predecessor entity.

1.19 “Technology” means, collectively, (a) Dyspareunia Product, (b) all compositions, components and formulations thereof, and (c) any and all methods of manufacture and uses of the foregoing.

1.20 “Third Party” means any Person other than Harrow, Elle or their respective Affiliates.

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1.21 "Valid Claim" means either (a) a claim of an issued and unexpired patent included within the Assigned Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a claim of a pending patent application included within the Assigned Patent Rights, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

## 2. Purchase and Sale of the Assets.

2.1 Assets. Subject to the terms and conditions of this Agreement, Harrow hereby agrees to, and hereby does, purchase from Elle, and Elle hereby agrees to, and hereby does, sell, convey, transfer and assign to Harrow, on the Effective Date, all of Elle's right, title and interest in and to the Assets, including without limitation all those assets described on Schedule 1 of the Patent Assignment attached hereto as Exhibit A. Concurrently with the execution of this Agreement, Elle shall deliver all required consents to Material Contracts (as defined below) as set forth on Schedule 3.7 hereof. To the extent necessary to comply with applicable privacy laws, Elle shall have the right to redact patient identifying information from any data or information transferred to Harrow.

2.2 No Assumption of Liabilities. Harrow shall not be obligated to assume or perform and is not assuming or performing any liabilities or obligations of Elle which relate to Elle's ownership of the Assets prior to the Effective Date, whether known or unknown, fixed or contingent, certain or uncertain, and regardless of when they are or were asserted, and Elle shall remain responsible for and shall promptly pay such liabilities.

2.3 Transfer Documents. The sale, conveyance, transfer and assignment of the Assets may be further evidenced by the due execution and delivery by the parties of any additional bills of sale, assignment or other title transfer documents and instruments as reasonably requested by Harrow. Without limiting the generality of the foregoing, (a) on the Effective Date, Elle shall duly execute and deliver to Harrow the patent assignment in the form attached as Exhibit A (the "Patent Assignment") evidencing the sale, conveyance, transfer and assignment of the Assigned Patent Rights from Elle to Harrow in accordance with this Agreement, and (b) at such time as reasonably requested by Harrow on or after the Effective Date, Elle shall duly execute and deliver to Harrow such additional bills of sale, assignment or other title transfer documents and instruments as reasonably requested by Harrow evidencing the sale, conveyance, transfer and assignment of the Assets in accordance with this Agreement.

2.4 Consideration. The consideration for the sale to Harrow of the Assets under this Agreement shall consist of the following (collectively, the "Purchase Price"):

2.4.1 Twenty-Five Thousand Dollars (\$25,000), payable within thirty (30) days after the Effective Date; and

2.4.2 the Net Sales Payment Consideration (as defined below).

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2.5 Allocation of Purchase Price. The Purchase Price shall be allocated, if an allocation is required, by Harrow within sixty (60) days following a determination that such allocation is required. After the Effective Date, Harrow and Elle shall make consistent use of any allocation required under Section 1060 of the Internal Revenue Code for all Tax purposes and in all filings, declarations and reports with the Internal Revenue Service or any other applicable taxing authority in respect thereof. In any and all actions, suits, proceedings, arbitration, or governmental or regulatory investigations or audits related to the determination of any Tax, neither Harrow nor Elle shall contend or represent that such allocation is not a correct allocation.

3. Representations and Warranties of Elle. Elle hereby represents and warrants to Harrow, except as indicated on the disclosure schedules, if any, attached to this Agreement, as follows:

3.1 Authority and Binding Effect. Elle has the full power and authority to execute and deliver this Agreement, the Patent Assignment and other documents and instruments contemplated hereby. This Agreement, the Patent Assignment and other documents and instruments contemplated hereby, and the consummation by Elle of its obligations contained herein and therein, have been duly authorized by all necessary actions of Elle, and this Agreement, the Patent Assignment and other documents and instruments contemplated hereby have been duly executed and delivered by Elle. This Agreement, the Patent Assignment and other documents and instruments contemplated hereby are valid and binding agreements of Elle, enforceable against Elle in accordance with their respective terms.

3.2 Organization and Standing. Elle is duly organized, validly existing and in good standing under the laws of the State of Delaware. Elle is qualified to do business in each jurisdiction where such qualification is necessary. Elle has the requisite corporate power and authority to conduct its business as now conducted, to own the Assets and to use such Assets in the conduct of its business.

3.3 Intellectual Property.

3.3.1 All Assigned Patent Rights as of the Effective Date are listed in Schedule 1 of the Patent Assignment attached hereto as Exhibit A.

3.3.2 Elle has good and marketable title to each of the Assets, and each of the Assets is held or controlled by Elle free and clear of any Encumbrances (including without limitation any distribution rights and royalty rights). Except as provided in the Material Contracts, all Assets will be fully transferable, alienable or licensable by Harrow without restriction and without payment of any kind to any Third Party.

3.3.3 All Assets (including without limitation the Assigned Patent Rights) are currently in compliance with applicable legal requirements (including payment of filing, examination and maintenance fees and proofs of use), and are not subject to any unpaid maintenance fees or taxes or actions falling due within ten (10) days after the Effective Date.

3.3.4 To the extent that any Assets were originally owned or created by or for any Person other than Elle, (a) Elle has obtained or will procure the complete, unencumbered and unrestricted right to effect the transfer of the Assets from Elle to Harrow and confirms that such transfer does not violate any such right to transfer; (b) no Third Parties have retained or otherwise have any rights or licenses with respect to the Assets; and (c) to the Knowledge of Elle, no valid basis exists for any such Person to challenge or object to this Agreement or the transactions contemplated herein.

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3.3.5 To Elle's Knowledge, Elle has not transferred ownership of, or granted any license of or right to use, or authorized the retention of any rights to use, to any Person any Assets.

3.3.6 To Elle's Knowledge, Elle is not required to make or accrue any royalty, milestone or other similar payment to any Third Party in connection with any of the Assets.

3.3.7 To Elle's Knowledge as of the Effective Date, none of the Assets transferred hereunder infringe upon or misappropriate the intellectual property of any Third Party.

3.4 Conflicts; Consents. The execution and delivery by Elle of this Agreement and the Patent Assignment, and the consummation of the transactions contemplated hereby, will not conflict with (i) any provision of the certificate of incorporation or bylaws of Elle, each as amended to date; (ii) Contracts to which Elle or any of its properties or assets (including intangible assets) is subject; or (iii) any judgment, order, decree, statute, law, ordinance, rule or regulation applicable to Elle or any of its properties or assets (tangible and intangible). Except as disclosed in Schedule 3.7, it is not necessary for Elle to take any action or to obtain any approval, consent or release by or from any Third Party, governmental or other, to enable Elle to enter into or perform its obligations under this Agreement and the Patent Assignment.

3.5 Litigation and Proceedings. There is no claim, action, suit, proceeding or investigation (or any counter or cross-claim in an action brought by or on behalf of Elle), whether at law or in equity, or before or by any governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, or before any arbitrator of any kind, that is pending or, to Elle's Knowledge, threatened, against Elle, which (i) could reasonably be expected to adversely affect Elle's ability to perform its obligations under this Agreement or the Patent Assignment or complete any of the transactions contemplated hereby; or (ii) involves the possibility of any judgment or liability, or which may become a claim, against the Assets, Harrow or its business. Elle is not subject to any judgment, order, writ, injunction, decree or award of any court, arbitrator or governmental department, commission, board, bureau, agency or instrumentality having jurisdiction over Elle or any of the Assets that affects, involves or relates to the Assets.

3.6 Compliance with Law/Permits. Elle is in compliance with all, and is not in violation of any, law, ordinance, order, decree, rule or regulation of any governmental agency or authority, the violation of or noncompliance with which could have a material adverse effect on Elle. No unresolved (i) charges of violations of laws or regulations relating to Elle's business have been made or threatened; (ii) proceedings or investigations relating to Elle's business are pending or have been threatened; and (iii) citations or notices of deficiency have been issued or have been threatened, against Elle relating to or arising out of its business by any governmental authorities.

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3.7 Contracts. Schedule 3.7 lists the Contracts to which Elle is a party as of the date hereof which arise out of or relate to the Assets by which any of the Assets are currently bound (the “Material Contracts”). Elle is not in violation of or in default under (nor is there existing conditions which with either the passage of time or giving of notice or both would cause such a violation or default under) any such Material Contract. Each such Material Contract is in full force and effect, and has a legal, valid and binding obligation Elle, and to Knowledge of Elle, each of the other parties thereto, and is enforceable in accordance with its terms. Elle has not received notice that it is in violation or breach of or in default under any such Material Contract. Except as set forth in Schedule 3.7, no such Material Contract has a provision that would require consent, notice or the payment of money or transfer of property as a result of the transactions contemplated herein.

3.8 Full Disclosure. The representations and warranties made by Elle in this Agreement and the schedules to be delivered pursuant to this Agreement do not contain any untrue statement of material fact or omit to state a material fact necessary to make any of them in the light of the circumstances in which they were made, not misleading.

3.9 No Broker. Elle has not retained or used the services of an agent, finder, or broker in connection with the transactions contemplated by this Agreement

4. Representations and Warranties of Harrow. Harrow represents and warrants to Elle as follows:

4.1 Authority and Binding Effect. Harrow has the full corporate power and authority to execute and deliver this Agreement and the Patent Assignment. This Agreement and the Patent Assignment, and the consummation by Harrow of its obligations contained herein and therein, have been duly authorized by all necessary corporate actions of Harrow, and this Agreement and the Patent Assignment have been duly executed and delivered by Harrow. This Agreement and the Patent Assignment are valid and binding agreements of Harrow, enforceable against Harrow in accordance with their respective terms.

4.2 Organization and Standing. Harrow is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and Harrow is qualified to do business in each jurisdiction where such qualification is necessary and where the failure to be so qualified would have a material adverse effect on Harrow. Harrow has the requisite corporate power and authority to conduct its business as now conducted.

4.3 Conflicts; Consents. The execution and delivery by Harrow of this Agreement and the Patent Assignment, and the consummation of the transactions contemplated hereby, will not give rise to a Conflict with respect to (i) any provision of the certificate of incorporation or bylaws of Harrow, each as amended to date; (ii) Contracts to which Harrow or any of its properties or assets (including intangible assets) is subject; or (iii) any judgment, order, decree, statute, law, ordinance, rule or regulation applicable to Harrow or any of its properties or assets (tangible and intangible), except in any such case where it would not have a material adverse effect on Elle’s rights under the Assets. It is not necessary for Harrow to take any action or to obtain any approval, consent, or release by or from any Third Party, governmental or other, to enable Harrow to enter into or perform its obligations under this Agreement and the Patent Assignment.

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4.4 Compliance with Law/Permits. Harrow is in compliance with all, and is not in violation of any, law, ordinance, order, decree, rule or regulation of any governmental agency or authority, the violation of or noncompliance with which could have a material adverse effect on Harrow. No unresolved (i) charges of violations of laws or regulations relating to Harrow' business have been made or threatened; (ii) proceedings or investigations relating to Harrow' business are pending or have been threatened; and (iii) citations or notices of deficiency have been issued or have been threatened, against Harrow relating to or arising out of its business by any governmental authorities, which have had or could reasonably be expected to have, individually or in the aggregate, a material adverse effect on Harrow.

4.5 No Broker. Harrow has not retained or used the services of an agent, finder, or broker in connection with the transactions contemplated by this Agreement.

## 5. Net Sales Payments.

### 5.1 Net Sales Payment Amounts.

5.1.1 Net Sales Payment Consideration. Subject to the provisions in this Section 5.1, on a Product-by-Product and country-by-country basis, Harrow shall pay to Elle, on a quarterly basis, seven and one-half percent (7½%) of Net Sales of any Dyspareunia Product during the applicable Payment Period and three and one-half percent (3½%) of Net Sales of any Other Product during the applicable Payment Period (the "Net Sales Payment Consideration").

5.1.2 Combination/Bundled Products. In the event that a Product is sold by Harrow, its Licensees or their respective Affiliates in combination with one or more products which is itself not a Product, then Net Sales shall be calculated by multiplying the sales price of such combination sale by the fraction  $A/(A+B)$  where A is the fair market value of the Product(s) and B is the fair market value of the other product(s) in the combination sale, each as reasonably determined by Harrow.

5.2 Reports and Net Sales Payments. Within seventy-five (75) days after the end of each calendar quarter during the applicable Payment Period, Harrow shall deliver to Elle a report setting forth for such calendar quarter (a) the calculation of the applicable Net Sales Payment Consideration; (b) the payments due under this Agreement for the sale of each Product; and (c) the applicable exchange rate as determined below. Harrow shall remit the total payments due for the sale of Products during such calendar quarter at the time such report is made. No such reports or payments shall be due for any Product before the First Commercial Sale of such Product. With respect to Net Sales received in United States dollars, all amounts shall be expressed in United States dollars. With respect to Net Sales received in a currency other than United States dollars, all amounts shall be expressed both in the currency in which the amount is invoiced (or received as applicable) and in the United States dollar equivalent. The United States dollar equivalent shall be calculated using the average of the exchange rate (local currency per US\$1) published in The Wall Street Journal, Western Edition, under the heading "Currency Trading" on the last business day of each month during the applicable calendar quarter.

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### 5.3 Payment Provisions.

5.3.1 Payment Terms. The Net Sales Payment Consideration shown to have accrued by each report provided for under Section 5.2 shall be due on the date such report is due. Payment of Net Sales Payment Consideration in whole or in part may be made in advance of such due date.

5.3.2 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all Net Sales Payment Consideration with respect to any country where a Product is sold, Harrow shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to Elle's account in a bank or other depository institution in such country. If the payment rate specified in this Agreement should exceed the permissible rate established in any country, the payment rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

5.3.3 Withholding Taxes. Harrow shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Harrow, its Licensees or its or their respective Affiliates, or any taxes required to be withheld by Harrow, its Licensees or its or their respective Affiliates, to the extent Harrow, its Licensees or their respective Affiliates pay to the appropriate governmental authority on behalf of Elle such taxes, levies or charges. Harrow shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of Elle by Harrow, its Licensees or its or their respective Affiliates. Harrow promptly shall deliver to Elle proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

5.4 Audits. Upon the written request of Elle and not more than once in each calendar year, Harrow shall permit an independent certified public accounting firm of nationally recognized standing selected by Elle and reasonably acceptable to Harrow, at Elle's expense, to have access during normal business hours to such of the financial records of Harrow as may be reasonably necessary to verify the accuracy of the Net Sales Payment Consideration reports hereunder for the eight (8) calendar quarters immediately prior to the date of such request (other than records for which Elle has already conducted an audit under this Section). If such accounting firm concludes that additional amounts were owed during the audited period, Harrow shall pay such additional amounts within thirty (30) days after the date Elle delivers to Harrow such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by Elle; provided, however, if the audit discloses that the Net Sales Payment Consideration payable by Harrow for such period are more than one hundred ten percent (110%) of the Net Sales Payment Consideration actually paid for such period, then Harrow shall pay the reasonable fees and expenses charged by such accounting firm. Elle shall cause its accounting firm to retain all financial information subject to review under this Section 5.4 in strict confidence; provided, however, that Harrow shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Harrow regarding such financial information. The accounting firm shall disclose to Elle only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. Elle shall treat all such financial information as Harrow' confidential information, and shall not disclose such financial information to any Third Party or use it for any purpose other than as specified in this Section 5.4.

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## 6. Post-Effective Date Covenants.

### 6.1 Harrow Diligence.

6.1.1 Harrow shall use commercially reasonable efforts (whether alone or with or through its Affiliates or Third Parties) to commercialize a Product.

6.1.2 As between the parties, Harrow shall control, at its sole expense, the preparation, filing, prosecution, maintenance and enforcement of the Assigned Patent Rights consistent with prudent business practices, and shall consider in good faith the interests of Elle.

6.2 Technology Transfer. Within thirty (30) days after the Effective Date, Elle shall transfer to Harrow all Assets, including without limitation all items described on Exhibit B.

### 6.3 Further Assistance.

6.3.1 Elle shall provide all cooperation reasonably requested by Harrow in connection with any effort by Harrow to establish, perfect, defend, or enforce its rights in or to the Assets (including without limitation the Assigned Patent Rights). Such cooperation shall include, without limitation, (a) executing such further assignments, transfers, licenses, releases and consents, and (b) providing such data and information, consulting with Harrow and executing and delivering all such further documents and instruments, in each case as requested by Harrow regarding the Assets (including without limitation the Assigned Patent Rights).

6.3.2 To the extent Elle cannot transfer and assign any of the Assigned Patent Rights, or any portion thereof, as of the Effective Date, then Elle shall assign and transfer the same at the first opportunity to do so. To the extent further transfer or assignment of any patents rights is required and Elle has not, within fifteen (15) days after the delivery of such assignment to Elle, (a) executed and returned to Harrow the form of assignment reasonably requested by Harrow, or (b) delivered to Harrow a written objection to Harrow' request, then Elle hereby irrevocably appoints Harrow as its attorney-in-fact with the right, authority, and ability to execute and enter into such assignment on behalf of Elle, subject to Section 9.2.3. Elle stipulates and agrees that such appointment is a right coupled with an interest and shall survive the incapacity or unavailability of Elle at any future time. To the extent that any of the Assigned Patent Rights cannot be assigned and transferred by Elle, then Elle hereby grants Harrow an irrevocable, worldwide, fully-paid up, royalty-free, exclusive license, with the right to sublicense through multiple tiers, under the Assigned Patent Rights for all purposes.

6.3.3 Elle shall provide all cooperation reasonably requested by Harrow, and shall provide all technical assistance and to support reasonably requested by Harrow, regarding (a) the exploitation of the Technology (including without limitation the research, development and production of any Product), and (b) applying for, obtaining and maintaining any and all approvals, licenses, registrations or authorizations necessary or desirable to test, market or commercialize the Technology (including without limitation any Product). Such cooperation shall include, without limitation, providing such data and information, consulting with Harrow and executing and delivering all such further documents and instruments, in each case as requested by Harrow regarding the Technology.

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6.3.4 Harrow shall own, and Elle hereby assigns to Harrow, all right title and interest in and to all results and other work product resulting from the activities described in this Section 6.3, together with all patent rights and other intellectual property rights therein and thereto; provided that any such assignment shall be subject to Section 9.2.3.

## 7. Indemnification.

7.1 Indemnification by Elle. Subject to the provisions of this Section 7, Elle shall indemnify, defend and hold harmless Harrow, its officers, directors, affiliates, agents, stockholders and representatives (collectively, the "Harrow Indemnitees"), from and against any and all losses, liabilities, damages and expenses (including without limitation reasonable expenses of investigation and attorneys' and consultants' fees and expenses in connection with any claim, demand, action or proceeding or settlement of any of any of the foregoing) (collectively, "Losses") incurred or suffered by an Harrow Indemnitee to the extent arising out of:

7.1.1 any breach of the representations and warranties of Elle set forth in this Agreement;

7.1.2 any breach of any covenant or agreement of Elle set forth in this Agreement or in any certificate, instrument, or other document delivered pursuant to this Agreement; and

7.1.3 the ownership or operation of the Assets prior to the Effective Date.

7.2 Indemnification by Harrow. Subject to the provisions of this Section 7, Harrow shall indemnify and hold harmless Elle, its officers, directors, affiliates, agents, stockholders and representatives (collectively, the "Elle Indemnitees"), from and against any and all Losses incurred or suffered by a Elle Indemnitee to the extent arising out of:

7.2.1 any breach of the representations and warranties of Harrow set forth in this Agreement;

7.2.2 any breach of any covenant or agreement of Harrow set forth in this Agreement or in any certificate, instrument, or other document delivered pursuant to this Agreement;

7.2.3 the ownership or operation of the Assets after the Effective Date or the manufacture, use, or sale of Product solely by Harrow, its Licensees or their respective Affiliates or use of Product by their customers.

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7.3 Offset. Harrow may offset against the Net Sales Payment Consideration or any other amounts due Elle from Harrow, any amounts owed to Harrow for indemnification under Section 7.1. The exercise of such offset by Harrow in good faith, whether or not ultimately determined to be justified, shall not constitute an event of default hereunder. Neither the exercise nor the failure to exercise, any such right of offset shall constitute an election of remedies or limit Harrow in any manner in the enforcement of any other remedies that may be available to it.

7.4 Procedure. A party seeking indemnification (the “Indemnitee”) shall promptly notify the other party (the “Indemnifying Party”) in writing of a claim or suit; provided that an Indemnitee’s failure to give such notice or delay in giving such notice shall not affect such Indemnitee’s right to indemnification under this Section 7 except to the extent that the Indemnifying Party has been prejudiced by such failure or delay. Harrow shall have the right to control the defense of all indemnification claims hereunder. Elle shall have the right to participate at its own expense in the claim or suit with counsel of its own choosing. Harrow shall consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. Elle shall cooperate with the Harrow as reasonably requested, at the Elle’s sole cost and expense. Harrow shall not settle any claim or suit with respect to which Elle is the Indemnifying Party without Elle’s prior written consent, which consent shall not be unreasonably withheld.

## 8. Confidentiality and Publication.

8.1 Confidential Information. During the term of this Agreement, and for a period of five (5) years following the expiration or earlier termination hereof, except as otherwise provided in this Section 8, Elle shall maintain in confidence all data and information comprising the Assets (the “Confidential Information”), and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, employees and contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, Elle shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement. Elle shall notify the other promptly upon discovery of any unauthorized use or disclosure of the Confidential Information.

8.2 Terms of this Agreement. Except as otherwise provided in this Section 8, neither party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other party; provided, however, that a party may disclose the terms or conditions of this Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, and (b) to a Third Party in confidence in connection with (i) an equity investment in such party, (ii) a merger, consolidation or similar transaction by such party, (iii) a permitted (sub)license under this Agreement, or (iv) the sale of all or substantially all of the assets of such party. Notwithstanding the foregoing, prior to execution of this Agreement, the parties have agreed upon the substance of information that can be used to describe the terms of this transaction, and each party may disclose such information, as modified by mutual agreement from time to time, without the other party’s consent.

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8.3 Permitted Disclosures. The confidentiality obligations contained in this Section 8 shall not apply to the extent that (a) a party is required (i) in the reasonable opinion of such party's legal counsel, to disclose information by applicable law, regulation, rule (including rule of a stock exchange or automated quotation system), order of a governmental agency or a court of competent jurisdiction or legal process, including tax authorities, or (ii) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that, to the extent practicable, such party shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or (b) a party can demonstrate that (i) the information was or became public knowledge, other than as a result of actions of such party in violation hereof; or (ii) the information was disclosed to the Recipient on an unrestricted basis from a source unrelated to any party to this Agreement and not under a duty of confidentiality to the other party. Notwithstanding anything to the contrary herein, Harrow may disclose the terms and conditions of this Agreement to any Person with whom Harrow has, or is proposing to enter into, a business relationship, as long as such Person has entered into a confidentiality agreement with Harrow.

8.4 Injunctive Relief. Each party acknowledges that it will be impossible to measure in money the damage to the other party if such party fails to comply with the obligations imposed by this Section 8, and that, in the event of any such failure, the other party may not have an adequate remedy at law or in damages. Accordingly, each party agrees that injunctive relief or other equitable remedy, in addition to remedies at law or damages, is an appropriate remedy for any such failure and shall not oppose the granting of such relief on the basis that the disclosing party has an adequate remedy at law. Each party agrees that it shall not seek, and agrees to waive any requirement for, the securing or posting of a bond in connection with the other party seeking or obtaining such equitable relief.

## 9. Term and Termination.

9.1 Term. The term of this Agreement shall commence on the Effective Date and continue until expiration of the last to expire Payment Period, unless earlier terminated as set forth below.

### 9.2 Termination.

9.2.1 If Harrow, whether alone or through an Affiliate or Third Party (including Mayfield), (a) fails to use commercially reasonable efforts to develop and commercialize a Product within the United States, or thereafter to use reasonable efforts to actively promote, market and sell such Product within the United States, or (b) before the third (3rd) anniversary of the Effective Date fails either to file an Investigational New Drug Application in the United States for a Product or to sell a Product for consideration, then Harrow shall provide written notice thereof to Elle and, unless the parties otherwise mutually agree in writing to extend the applicable time period, Elle shall have the right to terminate the Agreement by providing Harrow with thirty (30) days' prior written notice of termination within fifteen (15) days after Harrow' written notice described in this Section 9.2.1.

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9.2.2 If Mayfield fails to receive net proceeds of the sale of its equity securities to Third Parties of at least ten million dollars (\$10,000,000) in cash, whether individually or in the aggregate, by June 1, 2020, then (a) Harrow promptly shall provide written thereof to Elle and (b) Elle shall have the right to terminate this Agreement by providing Harrow with thirty (30) days' prior written notice of termination within fifteen (15) days after Harrow' notice described in clause (a).

9.2.3 If Elle terminates this Agreement pursuant to this Section 9.2, then Harrow shall (a) re-assign (or cause to be reassigned) the Assets to Elle and (b) grant to Elle a non-exclusive, worldwide, royalty-free license under the Improvement Patent Rights to make, have made, use, offer for sale, sell, and import Dyspareunia Product.

9.3 Survival. Expiration or termination of this Agreement shall be without prejudice to any rights which shall have accrued to the benefit of any party prior to such expiration. Without limiting the generality of the foregoing, Sections 3, 4, 5, 7, 8, 9.2.3, 9.3 and 10 shall survive any expiration or termination of this Agreement.

## 10. Miscellaneous.

10.1 Public Announcements. Neither party shall make any public announcements concerning matters concerning this Agreement or the negotiation thereof without the prior written consent of the other party unless such disclosure is required by law, in which case the announcing party shall provide the other party with reasonable notice of such disclosure.

10.2 Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that a party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction; provided that any such permitted assignee shall assume all obligations of its assignor under this Agreement including, in the case of an assignment by Harrow, its payment obligations to Elle in accordance with Section 5. Any purported assignment in violation of this Section 10.2 shall be void and of no legal effect.

10.3 Severability. Any provision of this Agreement which is illegal, invalid or unenforceable shall be ineffective to the extent of such illegality, invalidity or unenforceability, without affecting in any way the remaining provisions hereof.

10.4 Governing Law; Exclusive Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to the conflicts of law principles thereof. Each of the parties hereto irrevocably consents to the exclusive jurisdiction and venue of any federal court located in the Southern District of the State of California or state court in San Diego, California having jurisdiction, in connection with any matter based upon or arising out of this Agreement or the matters contemplated herein, agrees that process may be served upon them in any manner authorized by laws of the State of California for such persons and waives and covenants not to assert or plead any objection which they might otherwise have to such jurisdiction, venue and such process.

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10.5 Entire Agreement; Amendment. This Agreement, together with the Exhibit hereto, and each additional document, instrument or other agreement to be executed and delivered pursuant hereto constitute all of the agreements of the parties with respect to, and supersede all prior agreements and understandings relating to the subject matter of, this Agreement or the transactions contemplated by this Agreement. This Agreement may not be modified or amended except by a written instrument specifically referring to this Agreement signed by the parties hereto.

10.6 Waiver. No waiver by one party of the other party's obligations, or of any breach or default hereunder by any other party, shall be valid or effective, unless such waiver is set forth in writing and is signed by the party giving such waiver; and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such other party.

10.7 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by a party to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to Elle:           Elle Pharmaceutical, LLC

If to Harrow:       Harrow Health, Inc.  
12264 El Camino Real, Suite 350  
San Diego, California 92130  
Attention: Chief Executive Officer

10.8 Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS.]

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IN WITNESS WHEREOF, each party has caused a duly authorized representative to execute and deliver this Asset Purchase Agreement as of the Effective Date.

ELLE PHARMACEUTICAL, LLC

By: /s/ Elias Reichel

Name: Elias Reichel

Title: President

HARROW HEALTH, INC.

By: /s/ Mark Baum

Name: Mark Baum

Title: Chief Executive Officer

[Signature Page to Asset Purchase Agreement]

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EXHIBIT A

PATENT ASSIGNMENT

WHEREAS, ELLE PHARMACEUTICAL, LLC, a Delaware limited liability company (“Assignor”), with a place of business at 74 Chestnut St., Weston, Massachusetts 02493 is the owner of all rights, title, and interests in and to the patent applications and patents shown on the attached Schedule 1 (the “Assigned Patent Rights”); and

WHEREAS, HARROW HEALTH, INC., a Delaware corporation (“Assignee”), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130, desires to acquire the entire right, title, and interest in and to the Assigned Patent Rights and all the inventions and discoveries disclosed and/or claimed in the Assigned Patent Rights (the “Inventions”);

NOW THEREFORE, be it known that effective as of \_\_\_\_\_, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor hereby sells, assigns, transfers, and sets over unto Assignee (1) the entire right, title, and interest in all countries throughout the world in and to said Assigned Patent Rights and Inventions, including any renewals, revivals, reissues, reexaminations, extensions, continuations, continuations-in-part, and divisions of said Assigned Patent Rights and any substitute applications therefor; (2) the entire right to file patent applications (“New Applications”) in the name of Assignee or its designee on the aforesaid Inventions in all countries of the world; (3) the entire right, title, and interest in and to any patent which issued and may issue on the Inventions in any country, and any renewals, revivals, reissues, reexaminations, and extensions thereof, and any patents of confirmation, registration, and importation of the same; (4) the right to sue and recover for, and the right to profits or damages due or accrued in connection with, any and all past, present, or future infringements of the Assigned Patent Rights and Inventions; and (5) the entire right, title, and interest in all convention and treaty rights of all kinds, including without limitation all rights of priority in any country of the world, in and to the above Assigned Patent Rights and Inventions.

AND for the same consideration, said Assignor hereby covenants and agrees to and with said Assignee its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said Assignor is the sole and lawful owner of the entire right, title and interest in and to said Inventions and Assigned Patent Rights, and that the same are unencumbered and that said Assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said Assignor hereby covenants and agrees to and with said Assignee, its successors, legal representatives and assigns, that said Assignor will, whenever counsel of said Assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said Inventions and Assigned Patent Rights in any country, including interference proceedings, is lawful and desirable, or that any application for letters patent, or that any division, continuation or continuation-in-part of any application for letters patent or any reissue or extension of any letters patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of said Inventions and Assigned Patent Rights, without charge to said Assignee, its successors, legal representatives and assigns, but at the cost and expense of said Assignee, its successors, legal representatives and assigns.





EXHIBIT A: SCHEDULE 1  
ASSIGNED PATENT RIGHTS

EXHIBIT B  
CERTAIN ASSETS TO BE TRANSFERRED



CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER  
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Mark L. Baum, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Harrow Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in the report any change in this registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Mark L. Baum

Mark L. Baum  
Chief Executive Officer  
Principal Executive Officer

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CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER  
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Andrew R. Boll, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Harrow Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in the report any change in this registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Andrew R. Boll

Andrew R. Boll  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**CERTIFICATION REQUIRED BY  
SECTION 1350 OF TITLE 18 OF THE UNITED STATES CODE**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned hereby certifies in his capacity as the specified officer of Harrow Health, Inc. (the "Company"), that, to the best of his knowledge, the Quarterly Report of the Company on Form 10-Q for the fiscal quarter ended March 31, 2019 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented in the financial statements included in such report.

Date: May 9, 2019

*/s/ Mark L. Baum*

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Mark L. Baum  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 9, 2019

*/s/ Andrew R. Boll*

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Andrew R. Boll  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

This certification accompanies this Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

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