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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2017

Or

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

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

Commission File Number 001-36295

**Egalet Corporation**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**46-3575334**  
(I.R.S. Employer  
Identification No.)

**600 Lee Road  
Suite 100  
Wayne, PA**  
(Address of Principal Executive Offices)

**19087**  
(Zip Code)

Registrant's telephone number, including area code: **(610) 833-4200**

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

Title of each class	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

\_\_\_\_\_  
(Title of Class)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Emerging growth company ☒

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date.

Common Stock, \$0.001 par value

Shares outstanding as of May 10, 2017: 25,615,126

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Unless otherwise indicated or the context otherwise requires, references to the “Company”, “we”, “us” and “our” refer to Egalet Corporation and its subsidiaries. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense. Unless otherwise indicated, all statistical information provided about our business in this report is as of March 31, 2017.

# PART I

## ITEM 1. FINANCIAL STATEMENTS

### Egalet Corporation and Subsidiaries

#### Consolidated Balance Sheet s (in thousands, except share and per share data)

	<u>December 31, 2016</u>	<u>March 31, 2017</u> (unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 44,355	\$ 26,987
Marketable securities, available for sale	42,471	78,357
Accounts receivable	1,108	5,410
Inventory	1,700	1,511
Other current assets	-	197
Prepaid expenses and other current assets	2,537	1,378
Other receivables	1,001	1,049
Total current assets	93,172	114,889
Intangible assets, net	8,350	7,882
Property and equipment, net	12,709	11,857
Deposits and other assets	627	705
Total assets	<u>\$ 114,858</u>	<u>\$ 135,333</u>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	2,392	6,598
Accrued expenses	18,147	15,033
Deferred revenue	3,975	6,175
Debt - current	381	428
Total current liabilities	24,895	28,234
Debt - non-current portion, net	83,711	123,380
Deferred income tax liability	23	23
Derivative liability	12	-
Other liabilities	891	849
Total liabilities	109,532	152,486
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit)		
Common stock--\$0.001 par value; 75,000,000 shares authorized at December 31, 2016 and March 31, 2017; 25,189,125 and 25,407,427 shares issued and outstanding at December 31, 2016 and March 31, 2017, respectively	25	26
Additional paid-in capital	230,379	233,941
Accumulated other comprehensive (loss) income	100	194
Accumulated deficit	(225,178)	(251,314)
Total stockholders' equity (deficit)	5,326	(17,153)
Total liabilities and stockholders' equity	<u>\$ 114,858</u>	<u>\$ 135,333</u>

See accompanying notes to unaudited consolidated financial statements.

**Egalet Corporation and Subsidiaries**  
**Consolidated Statements of Operations (Unaudited)**  
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2016	2017
<b>Revenues</b>		
Net product sales	\$ 2,563	\$ 5,427
Collaboration revenues	100	—
Total revenue	2,663	5,427
<b>Cost and Expenses</b>		
Cost of sales (excluding amortization of product rights)	882	1,325
Amortization of product rights	501	503
General and administrative	5,998	8,491
Sales and marketing	6,202	9,258
Research and development	6,119	6,520
Total costs and expenses	19,702	26,097
Loss from operations	(17,039)	(20,670)
<b>Other (income) expense:</b>		
Change in fair value of derivative liability	(610)	(12)
Interest expense, net	2,309	4,534
Other gain	(3)	181
Loss (gain) on foreign currency exchange	(2)	—
	1,694	4,703
Loss before provision (benefit) for income taxes	(18,733)	(25,373)
Provision (benefit) for income taxes	(185)	—
Net loss	\$ (18,548)	\$ (25,373)
<b>Per share information:</b>		
Net loss per share of common stock, basic and diluted	\$ (0.76)	\$ (1.02)
Weighted-average shares outstanding, basic and diluted	24,406,247	24,766,147

See accompanying notes to unaudited consolidated financial statements.

**Egalet Corporation and Subsidiaries**  
**Consolidated Statements of Comprehensive Loss (Unaudited)**  
**(in thousands)**

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2017</b>
Net loss	\$ (18,548)	\$ (25,373)
Other comprehensive income (loss):		
Unrealized (loss) gain on available for sale securities	158	(35)
Foreign currency translation adjustments	588	129
Comprehensive loss	<u>\$ (17,802)</u>	<u>\$ (25,279)</u>

See accompanying notes to unaudited consolidated financial statements.

**Egalet Corporation and Subsidiaries**

**Consolidated Statements of Cash Flow s (Unaudited)**  
(in thousands)

	<b>Three Months Ended March 31, 2016</b>	<b>2017</b>
Operating activities:		
Net loss	\$ (18,548)	\$ (25,373)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	822	1,429
Change in fair value of derivative liability	(610)	(12)
Stock-based compensation expense	1,315	1,793
Noncash interest and amortization of debt discount	2,163	1,471
Amortization of premium on marketable securities	302	25
Deferred income taxes	(185)	—
Changes in assets and liabilities:		
Related party receivable	58	—
Accounts receivable	(534)	(4,302)
Inventory	(300)	189
Prepaid expenses and other current assets	(320)	962
Other receivables	(1,119)	(37)
Deposits and other assets	429	(76)
Accounts payable	(695)	4,293
Accrued expenses	130	(3,123)
Deferred revenue	(1,757)	2,200
Other current liabilities	56	1
Other liabilities	—	(46)
Net cash used in operating activities	<u>(18,793)</u>	<u>(20,606)</u>
Investing activities:		
Payments for purchase of property and equipment	(3,610)	(64)
Purchases of investments	(26,713)	(55,945)
Sales of investments	2,400	—
Maturity of investments	33,761	20,000
Net cash (used in) provided by investing activities	<u>5,838</u>	<u>(36,009)</u>
Financing activities:		
Net proceeds from issuance of common stock	—	1,007
Net proceeds from debt and royalty rights	—	38,304
Royalty payments in connection with the senior secured 13% notes	—	(146)
Net cash provided by financing activities	<u>—</u>	<u>39,165</u>
Effect of foreign currency translation on cash and cash equivalents	457	82
Net decrease in cash and cash equivalents	<u>(12,498)</u>	<u>(17,368)</u>
Cash at beginning of period	46,665	44,355
Cash at end of period	<u>\$ 34,167</u>	<u>\$ 26,987</u>
Supplemental disclosures of cash flow information:		
Cash interest payments	<u>\$ 2,042</u>	<u>\$ 3,784</u>

See accompanying notes to unaudited consolidated financial statements.

## **Egalet Corporation and Subsidiaries**

### **Notes to Unaudited Consolidated Financial Statements**

#### **1. Organization and Description of the Business**

##### **Organization and Business Overview**

Egalet Corporation (the “Company”) is a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. Given the need for acute and chronic pain products and the issue of prescription abuse, the Company is focused on bringing non-narcotic and abuse-deterrent formulations to patients and physicians. The Company is currently marketing SPRIX ® (ketorolac tromethamine) Nasal Spray (“SPRIX Nasal Spray”), OXAYDO ® (oxycodone HCl, USP) tablets for oral use only—CII (“OXAYDO”), and ARYMO™ ER (morphine sulfate) extended-release (“ER”) tablets (“ARYMO ER”).

SPRIX Nasal Spray is a nonsteroidal anti-inflammatory drug indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is an immediate release (“IR”) oxycodone product designed to discourage abuse via snorting, indicated for the management of acute and chronic moderate to severe pain where an opioid is appropriate.

On January 9, 2017, the U.S. Food and Drug Administration (“FDA”) approved ARYMO ER, the Company’s first product developed using its proprietary Guardian™ Technology. ARYMO ER is an ER morphine product formulated with abuse-deterrent (“AD”) properties and is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. On March 30, 2017, the Company began personal promotion of ARYMO ER to its target healthcare providers. The Company also has a pipeline of products in development using Guardian Technology. The Company plans to continue to grow through the revenues of its three commercial products, business development and leveraging its proprietary Guardian Technology.

##### **Liquidity**

The Company has incurred recurring operating losses since inception. As of March 31, 2017, the Company had an accumulated deficit of \$251.3 million and will require substantial additional capital to fund its commercialization strategies for ARYMO ER, SPRIX Nasal Spray and OXAYDO and its research and development of its proprietary product candidates. The Company reasonably expects that its cash and cash equivalents and marketable securities at March 31, 2017, will enable it to fund its operating expenses and capital expenditure requirements at least through June 30, 2018. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the development of its commercial and administrative organization and the research and development of its preclinical and clinical product candidates. As the Company continues to incur losses, a transition to profitability is dependent upon the successful commercialization of its approved products, the successful development, approval and commercialization of its product candidates and the achievement of a level of revenue adequate to support the Company’s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity, debt financings or other sources, including potential additional collaborations, until profitability is achieved, if ever. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

## 2. Summary of Significant Accounting Policies and Basis of Accounting

### Basis of Presentation

The unaudited consolidated financial statements are prepared in conformity with United States (“U.S.”) generally accepted accounting principles (“U.S. GAAP”) for interim financial information. Certain information and footnotes normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for quarterly reports on Form 10-Q. The Company’s consolidation policy requires the consolidation of entities where a controlling financial interest is held. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying consolidated financial information at March 31, 2017 and for the three months ended March 31, 2016 and 2017 is unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s consolidated financial position as of March 31, 2017 and the consolidated results of its operations, comprehensive loss and cash flows for the three months ended March 31, 2016 and 2017. The financial data and other information disclosed in these notes related to the three months ended March 31, 2016 and 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, any other interim periods or any future year or period. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2016 filed on March 13, 2017 with the SEC.

The Company’s significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016. Since the date of those financial statements, there have been no changes to the Company’s significant accounting policies.

### Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 became effective for the Company in the first quarter of 2017 and was applied using a modified retrospective transition approach. Under ASU 2016-09 the Company has elected to no longer estimate forfeiture rates as part of its stock-based compensation expense and will true up forfeitures as they occur. As a result of the adoption of ASU 2016-09, the Company recorded a cumulative adjustment of \$763,000 to accumulated deficit as of January 1, 2017.

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities*, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2017 and early adoption is



not permitted. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 simplifies the balance sheet classification of deferred taxes and requires that all deferred taxes be presented as noncurrent. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. The adoption of the update did not have a material effect on the Company's financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements—Going Concern*. ASU 2014-15 requires management of all entities to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued, and to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for the Company for annual reporting periods beginning in 2016 and for interim reporting periods starting in the first quarter of 2017. The adoption of this update did not have a material effect on the Company's financial statements.

In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers* (ASC 606): *Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers* (ASC 606): *Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12 *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards will be effective for the Company beginning in the first quarter of 2018. Early adoption is permitted.

As of March 31, 2017, the Company has not elected early adoption and has not concluded on an adoption method. The Company has formed a task force that is in the process of analyzing the Company's customer contracts and the potential impacts the standard may have on previously reported revenues and future revenues. The Company expects to recognize the majority of its revenue under such contracts earlier under ASC 606 than it would have recognized under current guidance. However, the Company is still evaluating the materiality of the impact on the consolidated financial statements and related disclosures.

### 3. Investments

#### Marketable Securities

Marketable securities consisted of the following at December 31, 2016:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	\$ 42,481	\$ 4	\$ (14)	\$ 42,471
Total	\$ 42,481	\$ 4	\$ (14)	\$ 42,471

Marketable securities consisted of the following as of March 31, 2017:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	\$ 78,402	\$ 1	\$ (46)	\$ 78,357
Total	\$ 78,402	\$ 1	\$ (46)	\$ 78,357

The fair value of marketable securities as of March 31, 2017 with a maturity of less than one year is \$56.2 million. The fair value of marketable securities with a maturity of greater than one year is \$22.2 million.

At March 31, 2017, the Company held 18 marketable securities that were in a continuous loss position for less than one year. The unrealized losses are immaterial in amount and are the result of current economic and market conditions and the Company has determined that no other than temporary impairment exists at March 31, 2017.

#### 4. Inventory

Inventory is stated at the lower of cost or market using actual cost net of reserve for excess and obsolete inventory. The following represents the components of inventory at December 31, 2016 and March 31, 2017:

(in thousands)	December 31, 2016	March 31, 2017
Raw materials	\$ 779	\$ 886
Finished goods	820	484
Deferred cost of sales	101	141
Total	\$ 1,700	\$ 1,511

The deferred costs of sales will be recognized upon release of the product to patients.

#### 5. Intangible Assets

The following represents the balance of the intangible assets at December 31, 2016:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	\$ 7,520	\$ (2,124)	\$ 5,396	5.00
SPRIX Nasal Spray product rights	4,620	(1,827)	2,793	3.00
IP R&D	161	—	161	Indefinite
Total	\$ 12,301	\$ (3,951)	\$ 8,350	

The following represents the balance of the intangible assets at March 31, 2017:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	\$ 7,537	\$ (2,398)	\$ 5,139	4.75
SPRIX Nasal Spray product rights	4,655	(2,075)	2,580	2.75
IP R&D	163	—	163	Indefinite
Total	<u>\$ 12,355</u>	<u>\$ (4,473)</u>	<u>\$ 7,882</u>	

There was no impairment to intangible assets in the three months ended March 31, 2016 or 2017.

*Collaboration and License Agreement with Acura Pharmaceuticals, Inc. (“Acura”)*

In January 2015, the Company entered into a Collaboration and License Agreement with Acura to commercialize OXAYDO™ (oxycodone hydrochloride) tablets containing Acura’s Aversion® Technology (the “OXAYDO License Agreement”). The Company paid Acura an upfront payment of \$5.0 million in January 2015 and a \$2.5 million milestone payment in October 2015 as a result of the first commercial sale of OXAYDO. The Company also incurred transaction costs of \$172,000 associated with the OXAYDO License Agreement. Refer to Note 12 — Acquisitions and License and Collaboration Agreements for additional details.

During the three months ended March 31, 2016 and 2017, the Company recognized amortization expense of \$274,000, and \$269,000, respectively, related to the OXAYDO product rights intangible asset.

*Purchase Agreement with Luitpold Pharmaceuticals, Inc. (“Luitpold”)*

In January 2015, the Company entered into and consummated the transactions contemplated by the Purchase Agreement with Luitpold to purchase SPRIX Nasal Spray (the “SPRIX Purchase Agreement”). Pursuant to the SPRIX Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX (ketorolac tromethamine) Nasal Spray for a purchase price of \$7.0 million. The Company recorded an intangible asset of \$4.6 million related to this transaction. Refer to Note 12 — Acquisitions and License and Collaboration Agreements for additional details.

During the three months ended March 31, 2016 and 2017, the Company recognized amortization expense of \$231,000 and \$234,000, respectively, related to the SPRIX Nasal Spray product rights intangible asset.

*In-Process Research and Development (“IP R&D”)*

In connection with the acquisition of Egalet A/S, the Company recognized an IP R&D asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications, the Guardian Technology. The IP R&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. As of December 31, 2016 and March 31, 2017, the carrying value of IP R&D was \$161,000, and \$163,000, respectively. The change in value was entirely due to fluctuation in foreign currency exchange rates.

## 6. Long-Term Debt

### *Hercules Loan and Security Agreement*

In January 2015, the Company entered into the Loan and Security Agreement, which was subsequently amended in December 2015 (as amended, the “Loan Agreement”), with Hercules Technology Growth Capital, Inc. (“Hercules”) and certain other lenders, pursuant to which the Company borrowed \$15.0 million under a term loan. The term loan bore an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. Under the Loan Agreement, the Company made interest only payments through July 1, 2016, and then was scheduled to repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date of July 1, 2018. In connection with the Loan Agreement, the Company granted a security interest in substantially all of its assets, excluding intellectual property and certain new drug applications and related approvals, as collateral for the obligations under the Loan Agreement.

On August 31, 2016, the Company repaid all outstanding obligations under the Loan Agreement with the proceeds of the 13% Notes (as defined below).

### *5.50% Convertible Senior Notes Due 2020 (the “5.50% Notes”)*

In April and May 2015, the Company issued through a private placement \$61.0 million in aggregate principal amount of the 5.50% Notes. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2015.

The 5.50% Notes are general, unsecured and unsubordinated obligations and rank senior in right of payment to all of the Company’s indebtedness that is expressly subordinated in right of payment to the notes. The 5.50% Notes rank equal in right of payment to the Company’s existing and future indebtedness and other liabilities that are not so subordinated. The 5.50% Notes are effectively subordinated to any of the Company’s future secured indebtedness to the extent of the value of the assets securing such indebtedness, and rank structurally junior to all indebtedness and other liabilities incurred by the Company’s subsidiaries, including trade payables. The 5.50% Notes rank equal in right of the payment to the 13% Notes described below.

The Company may not redeem the 5.50% Notes prior to maturity. The 5.50% Notes are convertible prior to maturity, subject to certain conditions described below, into shares of the Company’s common stock at an initial conversion rate of 67.2518 shares per \$1,000 principal amount of the 5.50% Notes (equivalent to an initial conversion price of approximately \$14.87 per share of common stock). This conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company will satisfy the conversion obligation by paying or delivering, as the case may be, cash, shares of the Company’s common stock or a combination thereof, at the Company’s election.

Holders may convert all or any portion of their 5.50% Notes, in multiples of \$1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding January 1, 2020 only under the following circumstances:

- on or after the date that is six months after the last date of original issuance of the 5.50% Notes, if the last reported sale price of the Company’s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the 5.50% Notes on each applicable trading day;
- during the five business day period after any five consecutive trading day period, (the “measurement period”), in which the trading price per \$1,000 principal amount of 5.50% Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company’s common stock and the conversion rate on each such trading day; or

- upon the occurrence of specified corporate events.

On or after January 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date (April 1, 2020), holders may convert all or any portion of their 5.50% Notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, and an interest make-whole payment in shares of the common stock, if applicable. If the Company satisfies the conversion obligation solely in cash or through payment and delivery, as the case may be, of a combination of cash and shares of the Company's common stock, the amount of cash and shares of common stock, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 50 trading day observation period.

In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its 5.50% Notes in connection with such a corporate event in certain circumstances. Holders will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, interest will be deemed to be paid in full, rather than cancelled, extinguished or forfeited from the consideration paid to the holders upon conversion of a 5.50% Note.

On or after the date that is six months after the last date of original issuance of the 5.50% Notes, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the 5.50% Notes on each applicable trading day, the Company will, in addition to the other consideration payable or deliverable in connection with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the 5.50% Notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company will pay any interest make-whole payment by delivering shares of the Company's common stock valued at 95% of the simple average of the daily volume weighted average price for the 10 trading days ending on and including the trading day immediately preceding the conversion date. Notwithstanding the foregoing, the number of shares the Company may deliver in connection with a conversion of the 5.50% Notes, including those delivered in connection with an interest make-whole payment, will not exceed 77.3395 shares of common stock per \$1,000 principal amount of 5.50% Notes, subject to adjustment. The Company will not be required to make any cash payments in lieu of any fractional shares or have any further obligation to deliver any shares of common stock or pay any cash in excess of the threshold described above. In addition, if in connection with any conversion the conversion rate is adjusted, then such holder will not receive the interest make-whole payment with respect to such 5.50% Note.

The Company accounts for convertible debt instruments by recording the liability and equity components of the convertible debt separately. The liability is computed based on the fair value of a similar debt instrument that does not include the conversion option. The liability component includes both the value of the embedded interest make-whole derivative and the carrying value of the 5.50% Notes. The equity component is computed based on the total debt proceeds less the fair value of the liability component. The equity component is also recorded as debt discount and amortized as interest expense over the expected term of the 5.50% Notes, using the effective interest method.

The liability component of the 5.50% Notes on the date of issuance was computed as \$41.6 million, including the value of the embedded interest make-whole derivative of \$0.9 million and the carrying value of the 5.50% Notes of \$40.6 million. Accordingly, the equity component on the date of issuance was \$19.4 million. The discount on the 5.50% Notes is being amortized to interest expense over the term of the 5.50% Notes, using the effective interest method.

The conversion criteria for the 5.50% Notes have not been met at March 31, 2017. Should the 5.50% Notes become convertible, management will determine whether the intent is to settle in cash which would result in the liability

component of the 5.50% notes being classified as a current liability and the equity component being presented as redeemable equity if the liability is considered current.

Transaction costs of \$4.1 million related to the issuance of the 5.50% Notes are allocated to the liability and equity components in proportion to the allocation of the proceeds and accounted for as debt discount and equity issuance costs, respectively. Approximately \$1.3 million of this amount was allocated to equity and the remaining \$2.8 million was recorded as debt discount.

The following table summarizes how the issuance of the 5.50% Notes is reflected in the Company's balance sheet at December 31, 2016 and March 31, 2017:

	December 31, 2016	March 31, 2017
(in thousands)		
Gross proceeds	\$ 61,000	\$ 61,000
Unamortized debt discount	(15,091)	(13,930)
Carrying value	\$ 45,909	\$ 47,070

On September 28, 2016, in connection with the issuance of the 13% Notes, the Company and its subsidiaries entered into Supplemental Indentures with the trustee for the 5.50% Notes pursuant to which the Company's subsidiaries became guarantors under the indenture guaranteeing the 5.50% Notes.

#### *13% Senior Secured Notes (the "13% Notes")*

In August 2016, the Company completed the initial closing (the "Initial Closing") of its offering (the "Offering") of up to \$80.0 million aggregate principal amount of its 13% senior secured notes (the "13% Notes") and entered into an indenture (the "Indenture") governing the 13% Notes with the guarantors party thereto (the "Guarantors") and U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent").

The Company issued \$40.0 million aggregate principal amount of the 13% Notes at the Initial Closing, and issued an additional \$40.0 million aggregate principal amount upon the FDA's approval of ARYMO™ ER in January 2017 (the "Second Closing"). Net proceeds from the Initial Closing and Second Closing were \$37.2 million and \$38.3 million, respectively, after deducting the estimated Offering expenses payable by the Company in connection with the Initial Closing and Second Closing. The 13% Notes were sold only to qualified institutional buyers within the meaning of Rule 144A under the Securities Act of 1933, as amended.

The Company has used and will use the net proceeds from the 13% Notes and the Royalty Rights (as defined below) to repay all outstanding obligations to Hercules under the Loan Agreement with Hercules, to support the commercialization of ARYMO ER, to support the development of Egalet-002 and for general corporate purposes.

Prior to the Second Closing, interest on the 13% Notes accrued at a rate of 13% per annum and was payable semi-annually in arrears on March 20 and September 20 of each year (each, a "Payment Date") commencing on March 20, 2017. On each Payment Date commencing on March 20, 2018, the Company was required to also pay an installment of principal of the 13% Notes pursuant to a straight-line fixed amortization schedule. Following Second Closing in January 2017, in lieu of the straight-line fixed amortization schedule, on each Payment Date commencing on March 20, 2018, the Company will pay an installment of principal on the 13% Notes in an amount equal to 15% (or 17% if certain sales targets are not met) of the aggregate net sales of OXAYDO, SPRIX Nasal Spray, ARYMO ER and Egalet-002, if approved, for the two consecutive fiscal quarterly period most recently ended, less the amount of interest payable on the 13% Notes on such Payment Date.

The 13% Notes are senior secured obligations of the Company and will be equal in right of payment to all existing and future pari passu indebtedness of the Company (including the Company's outstanding 5.50% Notes due 2020), will be senior in right of payment to all existing and future subordinated indebtedness of the Company, will have the benefit of a security interest in the 13% Notes collateral and will be junior in lien priority in respect of any collateral

that secures any first priority lien obligations incurred, which includes intellectual property (“IP”), from time to time in accordance with the Indenture. Following the Second Closing, the stated maturity date of the 13% Notes became September 30, 2033. Upon the occurrence of a Change of Control, subject to certain conditions, or certain Asset Sales events (each, as defined in the Indenture), holders of the 13% Notes may require the Company to repurchase for cash all or part of their 13% Notes at a repurchase price equal to 101.00% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase.

The Company may redeem the 13% Notes at its option, in whole or in part from time to time, prior to August 31, 2018, at a redemption price equal to 100.00% of the principal amount of the Notes being redeemed, plus accrued and unpaid interest, if any, through the redemption date, plus a make-whole premium computed using a discount rate equal to the treasury rate in respect of such redemption date plus 100 basis points. The Company may redeem the 13% Notes at its option, in whole or in part from time to time, on or after August 31, 2018 at a redemption price equal to: (i) from and including August 31, 2018 to and including August 30, 2019, 109.00% of the principal amount of the 13% Notes to be redeemed, (ii) from and including August 31, 2019 to and including August 30, 2020, 104.50% of the principal amount of the 13% Notes to be redeemed, and (iii) from and including August 31, 2020 and thereafter, 100.00% of the principal amount of the 13% Notes to be redeemed, in each case, plus accrued and unpaid interest to the redemption date. In addition, prior to August 31, 2018, the Company may redeem, at its option, up to 35% of the aggregate principal amount of the 13% Notes with the proceeds of one or more public or private equity offerings at a redemption price equal to 113.50% of the aggregate principal amount of the 13% Notes to be redeemed, plus accrued and unpaid interest to the date of redemption in accordance with the Indenture; provided that at least 65% of the aggregate principal amount of 13% Notes issued under the Indenture remains outstanding immediately after each such redemption and provided further that each such redemption occurs within 90 days of the date of closing of each such equity offering. No sinking fund is provided for the 13% Notes, which means that the Company is not required to periodically redeem or retire the 13% Notes.

The obligations of the Company under the Indenture and the 13% Notes are unconditionally guaranteed on a secured basis by the Guarantors. Under the terms of the Indenture, the Company may designate entities within its corporate structure as unrestricted subsidiaries, which entities will therefore not be guarantors provided that certain conditions set forth in the Indenture are met.

Pursuant to the Indenture, the Company and its restricted subsidiaries must also comply with certain affirmative covenants, such as furnishing financial statements to the holders of the 13% Notes, and negative covenants, including limitations on the following: the incurrence of debt; the issuance of preferred and/or disqualified stock; the payment of dividends, the repurchase of shares and under certain conditions making certain other restricted payments; the prepayment, redemption or repurchase of subordinated debt; the merger, amalgamation or consolidation involving the Company; engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Indenture.

The Indenture governing the 13% Notes contains customary events of default with respect to the 13% Notes (including the Company’s failure to make any payment of principal or interest on the 13% Notes when due and payable), and upon certain events of default occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 13% Notes by notice to the Company and the Trustee, may (subject to the provisions of the Indenture) declare 100% of the principal of and accrued and unpaid interest, if any, on all of the 13% Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, as well as the then-applicable optional redemption premium under the Indenture, will be due and payable immediately. In the case of certain events of bankruptcy, insolvency or reorganization involving the Company or a Restricted Subsidiary (as defined in the Indenture), the 13% Notes will automatically become due and payable.

In connection with the Initial Offering in August 2016, the Company entered into royalty rights agreements with each of the 13% Notes Purchasers pursuant to which the Company sold to such Purchasers the right to receive, in the aggregate, a payment equal to 1.5% of the aggregate net sales of OXAYDO and SPRIX Nasal Spray from the Initial Closing through December 31, 2019, inclusive (the “Royalty Rights”). Following the approval of ARYMO ER in January 2017, the Royalty Rights will continue through December 31, 2020 and the Company also entered into separate royalty rights agreements with each of the Purchasers pursuant to which the Company sold to such Purchasers the right



to receive 1.5% of the aggregate net sales of ARYMO ER payable from the date of first sale of ARYMO ER through December 31, 2020, inclusive. The royalty rights agreements also include other terms and conditions customary in agreements of this type.

The Royalty Rights were determined to be a freestanding element with respect to the 13% Notes and the Company is accounting for the Royalty Rights obligation relating to future royalties as a debt instrument. The Company has Royalty Rights obligations of \$4.9 million as of March 31, 2017, which are classified within current and non-current debt in the consolidated balance sheet.

The Company incurred fees and legal expenses of \$4.5 million in connection with the issuance of the 13% Notes, which have been recorded as a discount on the debt in the consolidated balance sheets and are amortized using the effective interest method. The Company calculated an effective interest rate of 15.9% as of March 31, 2017 based on its best estimate of future cash outflows.

The accounting for the 13% Notes requires the Company to make certain estimates and assumptions about the future net sales of OXAYDO, SPRIX Nasal Spray and ARYMO ER in the U.S. The estimates of the magnitude and timing of OXAYDO, SPRIX Nasal Spray and ARYMO ER net sales are subject to significant variability due to the recent product launch and the extended time period associated with the financing transaction, and are thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as the Company gains experience marketing OXAYDO, SPRIX Nasal Spray and ARYMO ER, which may result in future adjustments to the portion of the debt that is classified as a current liability, the amortization of debt issuance costs and discount as well as the accretion of the interest expense. Any such adjustments could be material. The fair value of the Royalty Rights associated with certain net product sales was estimated to be \$4.9 million using a probability-weighted present value analysis.

The following table summarizes how the issuance of the 13% Notes is reflected in the Company's consolidated balance sheets at December 31, 2016 and March 31, 2017:

	<u>December 31, 2016</u>	<u>March 31, 2017</u>
<b>(in thousands)</b>		
Gross proceeds	\$ 40,000	\$ 80,000
Unamortized debt discount	(5,187)	(8,236)
Carrying value	<u>\$ 34,813</u>	<u>\$ 71,764</u>

Current and non-current debt on the Company's consolidated balance sheets at December 31, 2016 and March 31, 2017 includes the carrying value of the 5.50% Notes and the 13% Notes, as well as \$3.3 million and \$5.0 million, respectively, for the Royalty Rights issued in connection with the 13% Notes.



## 7. Stockholders' Equity

On July 2, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (“2015 Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), under which the Company could, at its discretion, from time to time, sell shares of its common stock, for an aggregate offering price of up to \$30.0 million. The Company provided Cantor with customary indemnification rights, and Cantor was entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the 2015 Sales Agreement have been and, if there are additional sales under the 2015 Sales Agreement, will be made in transactions deemed to be “at the market offerings”, as defined in Rule 415 under the Securities Act of 1933, as amended.

The Company initiated sales of shares under the 2015 Sales Agreement in March 2017 and sold an aggregate of 187,972 shares of common stock through March 31, 2017, resulting in net proceeds of \$876,000 after deducting commissions of \$27,000. As of May 4, 2017, an additional 217,699 shares were sold under the 2015 Sales Agreement subsequent to March 31, 2017 resulting in net proceeds of \$1.0 million after deducting commissions of \$32,000 which will be recognized during the second quarter of 2017.

## 8. Fair Value Measurements

The Company measures certain assets and liabilities at fair value in accordance with ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

The following fair value hierarchy table presents information about each major category of the Company’s financial assets and liabilities measured at fair value on a recurring basis :

(in thousands)	Fair Value Measurements as of December 31, 2016			
	Level 1	Level 2	Level 3	Total 2016
<b>Assets</b>				
Cash equivalents (money market funds)	\$ 27,635	\$ —	\$ —	\$ 27,635
Marketable securities, available-for-sale	—	42,471	—	42,471
Total assets	\$ 27,635	\$ 42,471	\$ —	\$ 70,106
<b>Liabilities</b>				
Interest make-whole derivative	\$ —	\$ —	\$ 12	\$ 12
Total liabilities	\$ —	\$ —	\$ 12	\$ 12

(in thousands)	Fair Value Measurements as of March 31, 2017			
	Level 1	Level 2	Level 3	Total 2017
<b>Assets</b>				
Cash equivalents (money market funds)	\$ 11,854	\$ —	\$ —	\$ 11,854
Marketable securities, available-for-sale	—	78,357	—	78,357
Total assets	\$ 11,854	\$ 78,357	\$ —	\$ 90,211
<b>Liabilities</b>				
Interest make-whole derivative	\$ —	\$ —	\$ —	\$ —
Total liabilities	\$ —	\$ —	\$ —	\$ —

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 5.50% Notes prior to April 1, 2018, the Company will, in addition to the other consideration payable or deliverable in connection with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the 5.50% Notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company has determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability in the Company's consolidated balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's consolidated statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the March 31, 2017:

(in thousands)	Fair Value			
	December 31, 2016	Additions	Change in 2017	March 31, 2017
Interest make-whole derivative	12	\$ —	\$ (12)	\$ —
Total liabilities	\$ 12	\$ —	\$ (12)	\$ —

As of March 31, 2017, the fair value of the 5.50% Notes was estimated utilizing the binomial lattice tree model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value measurement was based on several factors including:

- Credit spread at the valuation date
- Discount yield as of the valuation date

The fair value and carrying value of the Company's 5.50% Notes at March 31, 2017 was as follows:

(in thousands)	Fair Value	Carrying Value	Face Value
5.50% Notes due April 1, 2020	\$ 48,288	\$ 47,070	\$ 61,000

The fair value of the Company's 13% Notes approximates its carrying value of \$71.8 million as the interest rate is reflective of the interest rates on debt the Company could currently obtain with similar terms and conditions and thus represents a Level 2 measurement within the fair value hierarchy.

## 9. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

(in thousands, except share and per share data)	Three Months Ended March 31,	
	2016	2017
Basic and diluted net loss per common share calculation:		
Net loss	\$ (18,548)	\$ (25,373)
Weighted average common stock outstanding	24,406,247	24,766,147
Net loss per share of common stock—basic and diluted	\$ (0.76)	\$ (1.02)

The following outstanding securities for the three months ended March 31, 2016 and 2017 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Three months ended 2016	March 31, 2017
Stock options outstanding	1,904,533	3,482,479
Unvested restricted stock awards	629,018	373,138
Common shares issuable upon conversion of the 5.50% Notes	4,102,360	4,102,360
Total	6,635,911	7,957,977

## 10. Stock-based Compensation

### 2013 Stock-Based Incentive Compensation Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Compensation Plan (as subsequently amended from time to time, the “2013 Plan”). Pursuant to the 2013 Plan, the compensation committee of the Company’s board of directors is authorized to grant equity-based incentive awards to its directors, executive officers and other employees and service providers, including officers, employees and service providers of its subsidiaries and affiliates. The number of shares of the Company’s common stock initially reserved for issuance under the 2013 Plan was 1,680,000 in the form of common stock, deferred stock, restricted stock, restricted stock units, stock options and stock appreciation rights. Share increases of 2,000,000 and 2,600,000 to the number of shares originally reserved for issuance under the 2013 Plan were authorized by the Company’s stockholders in June 2014 and June 2016, respectively. The amount, terms of grants and exercisability provisions are determined by the compensation committee, and in certain circumstances pursuant to delegated authority, the Company’s chief executive officer and chief financial officer, acting jointly. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the compensation committee. All stock options vest over time as stipulated in the individual award agreements. In September 2015, the compensation committee voted to amend the 2013 Plan to, among other things, allow for monthly vesting of stock options granted thereunder after the first annual vesting.

### 2017 Inducement Plan

In December 2016, the Company adopted its 2017 Inducement Plan (the “Inducement Plan”), which became effective in January 2017. Pursuant to the Plan, the Company’s compensation committee is authorized to grant equity-based incentive awards to its employees, including employees of its subsidiaries, who were not previously employees or non-employee directors of the Company or any of its subsidiaries (or who have had a bona fide period of non-employment with the Company and its subsidiaries) in compliance with Rule 5635(c)(4) of the Nasdaq Global Market. The number of shares of the Company’s common stock initially reserved for issuance under the Plan was 300,000, in the form of common stock, deferred stock, restricted stock, restricted stock units, stock options and stock appreciation rights. The amount, terms of grants and exercisability provisions are determined by the compensation committee of the Company’s board of directors. The term of stock options issued under the Inducement Plan may be up to 10 years, and stock options are exercisable in cash or as otherwise determined by the compensation committee of the Company’s board of directors. All stock options vest over time as stipulated in the individual award agreements.

## Employee Stock Purchase Plan

In January 2016, the Company established an Employee Stock Purchase Plan (the “Purchase Plan”), which was approved by the Company’s stockholders in June 2016. A total of 750,000 shares of common stock were originally approved for future issuance under the Purchase Plan pursuant to purchase rights granted to the Company’s employees. Under the Company’s Purchase Plan, eligible employees can purchase the Company’s common stock through accumulated payroll deductions at such times as established by the administrator. The Purchase Plan is administered by the compensation committee. Under the Purchase Plan, eligible employees may purchase the Company’s common stock at 85% of the lower of the fair market value of a share of the Company’s common stock on the first day of an offering period or on the last day of the offering period. Eligible employees may contribute up to 10% of their eligible compensation. A participant may purchase a maximum of 1,500 shares of common stock per offering period. Under the Purchase Plan, a participant may not accrue rights to purchase more than \$25,000 worth of the Company’s common stock for each calendar year in which such right is outstanding.

At the end of each offering period, shares of the Company’s common stock may be purchased at 85% of the lower of the fair market value of the Company’s common stock on the first or last day of the respective offering period. In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company’s common stock at the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the Purchase Plan is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option’s grant-date fair value and is recognized over the requisite service period of the option. The Company has estimated the option’s fair value to be \$1.15 using the Black-Scholes valuation model and recognized stock-based compensation expense of \$35,000 during the three months ended March 31, 2017, related to the Purchase Plan.

## Shares Available for Future Grant Under Equity Compensation Plans

As of March 31, 2017, the Company has reserved the following shares to be granted under its equity compensation plans:

Shares initially reserved under the 2013 Plan	1,680,000
Shares reserved under the Inducement Plan	300,000
Shares reserved under the Purchase Plan	750,000
Authorized increase to the 2013 Plan	4,600,000
Common stock options granted under the 2013 Plan	(3,690,364)
Common stock options granted under the Inducement Plan	(160,000)
Restricted stock awards granted under the 2013 Plan	(1,543,660)
Common stock issued under the Purchase Plan	(52,833)
Stock options and awards forfeited	360,737
Remaining shares available for future grant	<u>2,243,880</u>

The estimated grant-date fair value of the Company’s share-based awards is amortized ratably over the awards’ service periods. Stock-based compensation expense recognized was as follows:

(in thousands)	Three months ended March 31,	
	2016	2017
General and administrative	1,130	1,356
Sales and marketing	80	159
Research and development	105	278
Total stock based compensation expense	<u>1,315</u>	<u>1,793</u>

## Stock Options Granted Under Equity Compensation Plans

	Stock Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-average Remaining Contractual Term (in years)
Outstanding at December 31, 2016	2,952,572	\$ 8.63	
Granted	545,507	6.85	
Exercised	—	—	
Forfeited	(15,600)	5.92	
Cancelled	—	—	
Outstanding at March 31, 2017	3,482,479	\$ 8.37	8.84
Vested or expected to vest at March 31, 2017	3,482,479	\$ 8.37	8.84
Exercisable at March 31, 2017	749,271	\$ 9.09	8.07

The intrinsic value of the 3,482,479 options outstanding as of March 31, 2017 was \$50,000, based on a per share price of \$5.10, the Company's closing stock price on that date, and a weighted-average exercise price of \$8.37 per share.

The Company uses the Black-Scholes valuation model in determining the fair value of equity awards. For stock options granted to employees and directors with only service-based vesting conditions, the Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the requisite service period on a straight-line basis. The Company records the expense of services rendered by non-employees based on the estimated fair value of the stock option as of the respective vesting date. Further, the Company expenses the fair value of non-employee stock options that contain only service-based vesting conditions over the requisite service period of the underlying stock options. Following the adoption of ASU 2016-09 the Company no longer estimates forfeitures in calculating its stock-based compensation expense and adjusts each period to reflect actual forfeitures.

The per-share weighted-average grant date fair value of the options granted to employees during the three months ended March 31, 2017 was estimated at \$4.85 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2017
Risk-free interest rate	2.07 %
Expected term of options (in years)	6.25
Expected volatility	80.86 %
Dividend yield	—

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: The Company estimated the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin ("SAB") No. 107, "Share Based Payments", whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.
- Expected stock price volatility: The Company estimated the expected volatility based on its actual historical volatility of the Company's stock price. The Company calculated the historical volatility by using

daily closing prices over a period of the expected term of the associated award. A decrease in the expected volatility would have decreased the fair value of the underlying instrument.

Prior to the three months ended March 31, 2017, the Company estimated the expected volatility based on actual historical volatility of the stock price of similar companies with publicly-traded equity securities. The Company calculated the historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The impact of this change had an immaterial effect on the Company's financial results for the three months ended March 31, 2017.

- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.

As of March 31, 2017, there was \$12.4 million of total unrecognized stock-based compensation expense, related to unvested options granted under the 2013 Plan and the Inducement Plan, which will be recognized over the weighted-average remaining period of 3.01 years.

## Restricted Stock

A summary of the status of the Company's restricted stock awards at March 31, 2017 and of changes in restricted stock awards outstanding under the 2013 Plan for the three months ended March 31, 2017 is as follows:

	Number of Shares	Weighted-average Grant Date Fair Value per Share
Unvested at December 31, 2016	543,577	\$ 10.77
Granted	—	\$ —
Forfeited	—	\$ —
Vested restricted stock awards	(170,439)	\$ 11.65
Unvested at March 31, 2017	373,138	\$ 10.38

For stock awards that vest subject to the satisfaction of service requirements, stock-based compensation expense is measured based on the fair value of the award on the date of grant and is recognized as expense on a straight-line basis over the requisite service period. All of the restricted stock awards reflected above vest over time as stipulated in the individual award agreements. In the event of a change in control, the unvested awards will be accelerated and fully vested immediately prior to the change in control.

As of March 31, 2017, there was \$1.1 million of total unrecognized compensation expense, related to restricted stock under the 2013 Plan, which will be recognized over the weighted-average remaining period of 1.92 years.

## 11. Commitments and Contingencies

### Legal Proceedings

On January 27, 2017 and February 10, 2017, respectively, two putative securities class actions were filed in the U.S. District Court for the Eastern District of Pennsylvania that named as defendants Egalet Corporation and current officers Robert S. Radie, Stanley J. Musial, and Jeffrey M. Dayno. These two complaints, captioned Mineff v. Egalet Corp. et al., No. 2:17-cv-00390-MMB and Klein v. Egalet Corp. et al., No. 2:17-cv-00617-MMB, assert securities fraud claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 on behalf of putative classes of persons who purchased or otherwise acquired Egalet Corporation securities between December 15, 2015 and January 9, 2017. On May 1, 2017, the Court entered an order consolidating the two cases before it, appointing the Egalet Investor

Group (consisting of Johseph Spizzirri, Abdul Rahiman and Kyle Kobold) as lead plaintiff and approving their selection of lead and liaison counsel. The allegations in the complaints center on allegedly false and/or misleading statements and/or failures to disclose information about the likelihood that ARYMO ER would be approved for oral abuse-deterrent labeling. The Company disputes these allegations and intends to defend these actions vigorously. The Company cannot determine the likelihood of, nor can it reasonably estimate the range of, any potential loss, if any, from these lawsuits.

## **12. Acquisitions and License and Collaboration Agreements**

### *Collaboration and License Agreement with Acura*

In January 2015, the Company entered into the OXAYDO License Agreement with Acura to commercialize OXAYDO tablets containing Acura's Aversion Technology. OXAYDO (formerly known as Oxecta®) is currently approved by the FDA for marketing in the U.S. in 5 mg and 7.5 mg strengths, but was not actively marketed at the time of the OXAYDO License Agreement. Under the terms of the OXAYDO License Agreement, Acura transferred the approved New Drug Application ("NDA") for OXAYDO to the Company and the Company was granted an exclusive license under Acura's intellectual property rights for development and commercialization of OXAYDO worldwide in all strengths.

The Company paid Acura an upfront payment of \$5.0 million in January 2015 and a \$2.5 million milestone payment in October 2015 as a result of the first commercial sale of OXAYDO. In addition, Acura will be entitled to a one-time \$12.5 million milestone payment when OXAYDO net sales reach a level of \$150.0 million in a calendar year.

The Company has recorded a product rights intangible asset of \$7.7 million related to the arrangement, which includes \$172,000 of transaction costs related to the License Agreement. The intangible asset is being amortized over a useful life of 7 years, which coincides with the patent protection of the product in the U.S.

In addition, Acura receives from the Company, a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on OXAYDO net sales during such year. In any calendar year in which net sales exceed a specified threshold, Acura will receive a double digit royalty on all OXAYDO net sales in that year. The Company's royalty payment obligations commence on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering OXAYDO in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the U.S.). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by the Company to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor.

### *Purchase Agreement with Luitpold*

In January 2015, the Company entered into and consummated the transactions contemplated by the SPRIX Nasal Spray Purchase Agreement with Luitpold. Pursuant to the SPRIX Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX (ketorolac tromethamine) Nasal Spray for a purchase price of \$7.0 million. The Company concurrently purchased an additional \$1.1 million of glassware, equipment and active pharmaceutical ingredient ("API") from Luitpold and agreed to purchase an additional \$340,000 of API after closing.

Under the Company's purchase agreement with Luitpold it was assigned the license for SPRIX Nasal Spray from Recordati. S.p.A. Under the agreement with Recordati S.p.A., the Company is obligated to use best commercial efforts to market and sell SPRIX Nasal Spray and pay a fixed, single-digit royalty to Recordati S.p.A.

The Company accounted for the arrangement as a business combination and the purchase price has been allocated to the acquisition date fair values as follows:

(in thousands)	Purchase Price Allocation
Inventory	\$ 3,408
Property, plant & equipment	100
Finite lived intangible-intellectual property	4,620
Net assets acquired	<u>\$ 8,128</u>

### 13. Income Taxes

In accordance with ASC Topic No. 270 “*Interim Reporting*” and ASC Topic No. 740 “*Income Taxes*” (Topic No. 740) at the end of each interim period, the Company is required to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 31, 2016, the Company recorded a tax benefit of \$185,000. For the three months ended March 31, 2017, the Company had no tax provision since it is now in a full valuation allowance for federal, foreign and state purposes. The Company maintains a full valuation allowance against all deferred tax assets as management has determined that it is not more likely than not that the Company will realize these future tax benefits. The Company will continue to monitor and determine whether valuation allowances are appropriate.



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

*The following discussion and analysis of our financial condition and result of operations should be read in conjunction with our 2016 Annual Report on Form 10-K filed with the Securities and Exchange Commission.*

### Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “potential,” “continue,” “seek to” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain, including, but not limited to, risks related to: our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our current and future indebtedness; our ability to obtain additional financing; the level of commercial success of our products and, if approved, our product candidates; our ability to execute on our sales and marketing strategy, including developing relationships with customers, physicians, payors and other constituencies; the continued development of our currently limited commercialization capabilities, including sales and marketing capabilities and the outcome of the internalization of our previously external sales force; the success of competing products that are or become available; the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of our products and product candidates; the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and any related restrictions, limitations and/or warnings in the product label under any approval we may obtain; the performance of third parties, including contract research organizations, manufacturers and collaborators; our success with regard to any business development initiatives; the success and timing of our preclinical studies and clinical trials; our ability to recruit or retain key scientific or management personnel or to retain our executive officers; regulatory developments in the U.S. and foreign countries; obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology; our ability to operate our business without infringing the intellectual property rights of others; recently enacted and future legislation regarding the healthcare system; the success of competing products that are or become available; and our ability to integrate and grow any businesses or products that we may acquire.

You should refer to the “Risk Factors” section of our most recent Annual Report on Form 10-K as filed with the SEC, which are incorporated herein by reference, for a discussion of additional important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements included herein or that may be made elsewhere from time to time by, or on behalf of, us. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

### Our Business

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. Given the need for acute and chronic pain products and the issue of prescription abuse, we are focused on bringing non-narcotic and abuse-deterrent opioid formulations to patients and physicians. We are currently marketing SPRIX® (ketorolac tromethamine) Nasal Spray (“SPRIX Nasal Spray”), OXAYDO® (oxycodone HCl, USP) tablets for oral use only—CII (“OXAYDO”) and ARYMO™ ER (morphine sulfate) extended-release (“ER”) tablets (“ARYMO ER”).

SPRIX Nasal Spray is the first and only approved nasal spray formulation of a nonsteroidal anti-inflammatory

drug (“NSAID”), in this case, ketorolac, used for short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. While providing analgesia at the opioid level, SPRIX Nasal Spray does not have issues of misuse or abuse common to opioids or some of the common opioid related side effects.

OXAYDO is an immediate-release (“IR”) oral formulation of oxycodone indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. It was designed to discourage abuse via the route of snorting. We are targeting high-decile of pain medicine prescribers who have a history of prescribing SPRIX and healthcare providers who have a history of prescribing intramuscular injections of ketorolac with our sales force. In addition, we have sought to augment our commercial reach in other markets, including through our agreements for SPRIX Nasal Spray with Teva Pharmaceutical Industries Ltd. in the Middle East and with Septodont, Inc. (“Septodont”) focused on dentists in the U.S.

On January 9, 2017, the U.S. Food and Drug Administration (“FDA”) approved ARYMO ER, our first product developed using our proprietary Guardian™ Technology. ARYMO ER is an ER morphine product formulated with abuse-deterrent (“AD”) properties and approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. On March 30, 2017, we began personal promotion of ARYMO ER to our target healthcare providers.

In conjunction with the ARYMO ER launch, we transitioned our salesforce, which was internalized in January 2017, into two separate teams. A team of 32 territory managers are focusing on educating approximately 4,500 healthcare providers about SPRIX Nasal Spray, and another team of 50 territory managers are promoting OXAYDO and ARYMO ER to approximately 6,000 healthcare providers. In addition, we have an account management team calling on commercial and government payers, and a trade team focused on channel partners.

To expand the commercial opportunity for OXAYDO, we submitted a prior approval supplement to support approval of 10 and 15 mg dosage strengths which was accepted on April 18, 2017. In addition, in December 2016, we filed a supplemental new drug application (“sNDA”) for OXAYDO with the FDA to support an abuse-deterrent label claim for the intravenous route of abuse. The application was based on data that was presented at the PAINWeek conference in September 2016.

Beyond our commercial programs, we have a pipeline of products developed using our Guardian Technology. Egalet-002, an AD, ER, oral oxycodone formulation currently in Phase 3 studies, is in development for the same indication as ARYMO ER. We will be delaying indefinitely our previously-announced anticipated 2019 filing date for the Egalet-002 New Drug Application. We are seeking partners for our earlier programs, Egalet-003, an AD stimulant, and Egalet-004, an AD, ER hydrocodone.

We are focusing our business development on augmenting our product portfolio through potential in-licenses and product acquisitions; enhancing the opportunities for our existing products through partnerships that access physicians and patients outside of our commercial focus in the United States or markets outside the United States; and developing partnerships to leverage our Guardian Technology by collaborating on our current product candidates or exploring new product opportunities.

#### *Financial Operations*

Our net losses for the three months ended March 31, 2016 and 2017 were \$18.5 million and \$25.4 million, respectively. We recognized revenues in the three months ended March 31, 2016 and 2017 of \$2.7 million and \$5.4 million, respectively. As of March 31, 2017, we had an accumulated deficit of \$251.3 million. We expect to incur significant expenses and operating losses for the foreseeable future as we incur significant commercialization expenses as we continue to grow our sales, marketing and distribution infrastructure to sell our commercial products in the U.S. Additionally, we expect to continue to scale-up manufacturing capabilities, protect and expand our intellectual property portfolio, hire additional personnel and continue the development and clinical trials of, and seek regulatory approval for, our product candidates.

Until we become profitable, if ever, we will seek to fund our operations primarily through public or private equity or debt financings or other sources. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a material adverse effect on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

### Critical Accounting Policies and Significant Judgments and Estimates

We believe there have been no significant changes in our critical accounting policies and significant judgments and estimates as discussed in our audited consolidated financial statements and the notes thereto for the year ended December 31, 2016 filed on March 13, 2017.

### Results of Operations

#### Comparison of the three months ended March 31, 2016 and 2017

(in thousands)	Three Months Ended March 31,		
	2016	2017	Change
<b>Revenues</b>			
Net product sales	\$ 2,563	\$ 5,427	\$ 2,864
Collaboration revenues	100	—	(100)
Total revenue	2,663	5,427	2,764
<b>Cost and Expenses</b>			
Cost of sales (excluding amortization of product rights)	882	1,325	443
Amortization of product rights	501	503	2
General and administrative	5,998	8,491	2,493
Sales and marketing	6,202	9,258	3,056
Research and development	6,119	6,520	401
Total costs and expenses	19,702	26,097	6,395
Loss from operations	(17,039)	(20,670)	(3,631)
<b>Other (income) expense:</b>			
Change in fair value of derivative liability	(610)	(12)	598
Interest expense, net	2,309	4,534	2,225
Other (gain) loss	(3)	181	184
Gain on foreign currency exchange	(2)	—	2
	1,694	4,703	3,009
Loss before provision (benefit) for income taxes	(18,733)	(25,373)	(6,640)
Provision (benefit) for income taxes	(185)	—	185
Net loss	\$ (18,548)	\$ (25,373)	\$ (6,825)

#### Net Product Sales

Net product sales increased from \$2.6 million for the three months ended March 31, 2016 to \$5.4 million for the three months ended March 31, 2017. Net product sales for the three months ended March 31, 2016 consisted of \$2.2 million for SPRIX Nasal Spray and \$417,000 for OXAYDO. Net product sales for the three months ended March 31, 2017 consisted of \$4.1 million for SPRIX Nasal Spray and \$1.3 million for OXAYDO.

#### Cost of Sales (excluding Amortization of Product Rights)

Cost of sales (excluding amortization of product rights) increased from \$882,000 for the three months ended March 31, 2016 to \$1.3 million for the three months ended March 31, 2017.

Cost of sales for SPRIX Nasal Spray for the three months ended March 31, 2016 of \$773,000 reflects the fair value of finished goods inventory assumed as part of the SPRIX Nasal Spray acquisition. Cost of sales for SPRIX Nasal Spray for the three months ended March 31, 2017 of \$1.1 million reflected the average cost of inventory produced and dispensed to patients during the three months ended March 31, 2017 and included a write-down of SPRIX Nasal Spray inventory of \$427,000.

Cost of sales for OXAYDO for the three months ended March 31, 2016 and 2017 were \$100,000 and \$160,000, respectively. Cost of sales for OXAYDO in both periods reflected the average costs of inventory dispensed to patients.

#### *Amortization of Product Rights*

Amortization of product rights increased from \$501,000 for the three months ended March 31, 2016 to \$503,000 for the three months ended March 31, 2017. Amortization of product rights was comprised of \$270,000 for the OXAYDO and \$231,000 for the SPRIX Nasal Spray intangible assets in the three months ended March 31, 2016, and \$269,000 for the OXAYDO and \$234,000 for the SPRIX Nasal Spray intangible assets in the three months ended March 31, 2017.

#### *General and Administrative Expenses*

General and administrative expenses increased by \$2.5 million, or 41.6% from \$6.0 million for the three months ended March 31, 2016 to \$8.5 million for the three months ended March 31, 2017. The increase was attributable to increases in employee salary and benefit expenses of \$544,000, increases in stock-based compensation expense of \$218,000 and increases in professional and administrative fees of \$634,000. For the three months ended March 31, 2016 general and administrative expenses were lower due to a regulatory filing fee refund of \$800,000.

#### *Sales and Marketing Expenses*

Sales and marketing expenses increased \$3.1 million or 49.3%, from \$6.2 million for the three months ended March 31, 2016 to \$9.3 million for the three months ended March 31, 2017. Approximately \$1.1 million of the increase was attributable to the expansion of our commercial organization and costs associated with the internalization of our previously contracted sales organization in January 2017. There were also increases in sales and marketing launch preparation expenses related to ARYMO ER of \$1.1 million and \$923,000 related to recruiting, sales force training and other expenses.

#### *Research and Development Expenses*

Research and development expenses increased by \$401,000, or 6.6% from \$6.1 million for the three months ended March 31, 2016 to \$6.5 million for the three months ended March 31, 2017. This increase was driven primarily by increases in developments costs for Egalet-002 of \$1.1 million and increases in employee salary and benefit expenses of \$236,000. These increases were partially offset by decreases in our development costs for ARYMO ER and OXAYDO of \$415,000 and \$236,000, respectively and decreases in other non-product related expenses of \$428,000.

#### *Change in fair value of derivative liability*

The interest make whole provision of our 5.50% convertible senior notes due April 1, 2020 (the “5.50% Notes”) is subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations and comprehensive loss as a change in fair value of the derivative liability. During the three months ended March 31, 2016 and 2017 we had a gain of \$610,000 and \$12,000, respectively, as a result of the change in the fair value of our derivative liability. The change in fair value of the derivative liability is due primarily to changes in the value of our common stock during the three months ended March 31, 2016 and 2017.

### *Interest expense*

Interest expense was \$2.3 million for the three months ended March 31, 2016, and \$4.5 million for the three months ended March 31, 2017. The increase was driven primarily by the issuance of the 13% Notes (as defined below) in August 2016 and January 2017. The interest expense of \$4.6 million for the three months ended March 31, 2017 includes non-cash interest and amortization of debt discount totaling \$1.8 million.

### *Gain on Foreign Currency Exchange*

For the three months ended March 31, 2016, we recognized a gain on foreign currency exchange of \$2,000. For the three months ended March 31, 2017, there was no financial impact. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2016 when compared to 2017.

### *Provision (benefit) for Income Taxes*

We had a benefit for income taxes of \$185,000 and \$0 for the three months ended March 31, 2016 and 2017, respectively. The income tax benefit for the three months ended March 31, 2016 relates to a state tax benefit associated with the 5.50% Notes. We had no tax provision for the three months ended March 31, 2017 since we are now in a full valuation allowance for federal and state purposes.

## **Liquidity and Capital Resources**

Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of \$18.5 million and \$25.4 million for the three months ended March 31, 2016 and 2017, respectively. Our operating activities used \$18.8 million of cash and \$20.6 million of cash during the three months ended March 31, 2016 and 2017, respectively. At March 31, 2017, we had an accumulated deficit of \$251.3 million, a working capital surplus of \$86.7 million and cash, cash equivalents and marketable securities totaling \$105.3 million.

From our inception through our initial public offering (“IPO”) on February 11, 2014, we received gross proceeds of \$31.1 million from the issuance of preferred stock and convertible debt.

In January 2015, we entered into the Loan Agreement with Hercules and certain other lenders, pursuant to which we borrowed \$15.0 million under a term loan. In August 2016, we repaid all outstanding obligations under the Loan Agreement, using the proceeds from the 13% Notes. Refer to Note 6 — Long-term Debt in the Notes to our Unaudited Consolidated Financial Statements for additional information.

In April and May 2015, we issued through a private placement \$61.0 million in aggregate principal amount of the 5.50% Notes. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing on October 1, 2015. Refer to Note 6- Long-term debt for additional information.

In July 2015, we completed an underwritten public offering of 7,666,667 shares of common stock (including the exercise in full of the underwriters’ option to purchase additional shares) at an offering price of \$11.25 per share for gross proceeds of \$86.3 million. The net offering proceeds from the sale were \$80.8 million, after deducting underwriting discounts and commissions of \$5.2 million and offering costs of \$293,000.

Through December 31, 2015 we financed our operations with the \$4.1 million in payments from our collaborative research and development agreements along with aggregate upfront and milestone payments of \$20.0 million under our collaborative research and license agreement with Shionogi Limited.

In August 2016, we issued \$40.0 million in aggregate principal amount of the 13% Senior Secured Notes and issued another \$40.0 million in aggregate principal amount following FDA approval of ARYMO ER in January 2017 (the “13% Notes”). Interest on the 13% Notes accrues at a rate of 13% per annum and is payable semi-annually in

arrears on March 20 and September 20 of each year (each, a “Payment Date”) commencing on March 20, 2017. On each Payment Date commencing on March 20, 2018, we will also pay an installment of principal on the 13% Notes in an amount equal to 15% (or 17% if certain sales targets are not met) of the aggregate net sales of OXAYDO (oxycodone HCl, USP) tablets for oral use only – CII, SPRIX Nasal Spray, ARYMO ER and Egalet-002, if approved, for the two consecutive fiscal quarter period most recently ended, less the amount of interest paid on the Notes on such Payment Date.

In March 2017, we initiated sales of shares under its July 2015 Controlled Equity Offering Sales Agreement (“2015 Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”) and sold an aggregate of 187,972 shares of common stock through March 31, 2017, resulting in net proceeds of \$876,000 after deducting commissions of \$27,000. As of May 4, 2017, an additional 217,699 shares were sold under the 2015 Sales Agreement subsequent to March 31, 2017 resulting in net proceeds of \$1.0 million after deducting commissions of \$32,000 which will be recognized during the second quarter of 2017. Under the 2015 Sales Agreement, we may, at our discretion, from time to time sell shares of our common stock, for an aggregate offering price of up to \$30.0 million (inclusive of amounts sold to date). We provided Cantor with customary indemnification rights, and Cantor is entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the 2015 Sales Agreement have been made and, if there are additional sales under the 2015 Sales Agreement, will be made in transactions deemed to be “at the market offerings”, as defined in Rule 415 under the Securities Act of 1933, as amended.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least June 30, 2018.

### **Cash Flows**

The following table summarizes our cash flows for the three months ended March 31, 2016 and 2017:

(in thousands)	Three Months Ended March 31,	
	2016	2017
Net cash provided by (used in):		
Operating activities	\$ (18,793)	\$ (20,606)
Investing activities	5,838	(36,009)
Financing activities	—	39,165
Effect of foreign currency translation on cash	457	82
Net decrease in cash	<u>\$ (12,498)</u>	<u>\$ (17,368)</u>

### **Cash Flows from Operating Activities**

Net cash used in operating activities for the three months ended March 31, 2016 was \$18.8 million and consisted primarily of a net loss of \$18.5 million and net cash outflows from changes in operating assets and liabilities of \$4.1 million, which consisted of a decrease in deferred revenue of \$1.8 million, an increase in other receivables of \$1.1 million, a decrease in accounts payable of \$695,000 and an increase in accounts receivable of \$534,000. These cash outflows were partially offset by non-cash interest and amortization of debt discount of \$2.2 million and non-cash expense for stock-based compensation expense of \$1.3 million.

Net cash used in operating activities for the three months ended March 31, 2017 was \$20.6 million and consisted primarily of a net loss of \$25.4 million. The net loss was partially offset by \$4.5 million net non-cash adjustments to reconcile net loss to net cash used in operations, which included stock-based compensation expense of \$1.8 million, non-cash interest and amortization of debt discount of \$1.4 million and depreciation and amortization expense of \$1.3 million. Net cash outflows from changes in operating assets and liabilities of \$276,000 consisted of an increase in accounts receivable of \$4.3 million and a decrease in accrued expenses of \$3.5 million, offset by an increase in accounts payable of \$4.3 million and a decrease in deferred revenue of \$2.2 million.

### *Cash Flows from Investing Activities*

Net cash provided by investing activities for the three months ended March 31, 2016 was \$5.8 million and consisted of \$33.8 million from maturity of investments, \$2.4 million from the sale of investments, partially offset by \$26.7 million for the purchase of investments and \$3.6 million for the purchase of property and equipment.

Net cash used in investing activities for the three months ended March 31, 2017 was \$36.0 million and consisted of \$55.9 million used to purchase investments, offset by \$20.0 million for the maturity of investments.

### *Cash Flows from Financing Activities*

There was no cash provided by or used in financing activities for the three months ended March 31, 2016.

Net cash provided by financing activities was \$39.2 million for the three months ended March 31, 2017 and consisted of \$38.3 million in net proceeds from the issuance of the 13% Notes and Royalty Rights and \$876,000, in net proceeds from the issuance of common stock pursuant to our “at-the-market” offering.

### **Operating and Capital Expenditure Requirements**

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, sales and marketing expenses, research and development expenses, commercial infrastructure development, legal and other regulatory expense, business development opportunities and general overhead costs, including interest and principal repayments on our outstanding debt. We expect our cash expenditures to increase in the near term as we continue to grow our commercialization activities around SPRIX Nasal Spray, OXAYDO and ARYMO ER.

Because our approved products are in the early stages of commercialization that will require significant investment and our product candidates are in various stages of clinical and preclinical development, and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the commercialization and development of our products and product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. The indenture governing the 13% Notes contains covenants that restrict our ability to issue additional indebtedness. Although our ability to issue additional indebtedness is significantly limited by such covenants, if we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We may also seek to raise additional financing through the issuance of debt which, if available and permitted pursuant to the documents governing the 13% Notes and our other existing indebtedness, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least June 30, 2018. However, our future operating and capital requirements will depend on many factors, including:

- the commercial success of our approved products;
- the cost of our current commercialization activities, including marketing, sales and distribution costs, as well as commercialization activities for any future product candidates that are approved for sale; our ability to establish collaborations or product acquisitions on favorable terms, if at all;



- the costs, timing and outcome of regulatory review;
- the results of our clinical trials;
- the scope, progress, results and costs of product development of our product candidates; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending intellectual property-related claims.

Please see the “Risk Factors” section of our most recent Annual Report on Form 10-K filed with the SEC on March 13, 2017 for additional risks associated with our substantial capital requirements.

### Contractual Obligations and Commitments

The following table represents our contractual obligations and commitments as of March 31, 2017:

(in thousands)	Payments Due By Period				
	Total	Less than		More than	
		1 year	1 to 3 years	3 to 5 years	5 years
Operating lease obligations(1)	\$ 2,785	\$ 671	\$ 1,061	\$ 1,053	\$ —
13% Notes (2)	125,367	10,544	35,793	60,711	18,319
5.50% Notes (3)	72,743	3,355	6,710	62,678	—
Manufacturing Agreement (4)	16,410	2,010	7,200	7,200	—
<b>Total</b>	<b>\$217,305</b>	<b>\$16,580</b>	<b>\$50,764</b>	<b>\$131,642</b>	<b>\$18,319</b>

- (1) Operating lease obligations reflect our obligation to make payments in connection with the leases for our office space.
- (2) On August 31, 2016, we completed the initial closing (the “Initial Closing”) of our offering of up to \$80.0 million aggregate principal amount of our 13% Notes. We issued \$40.0 million aggregate principal amount of the 13% Notes at the Initial Closing, and issued an additional \$40.0 million aggregate principal amount of the 13% Notes upon FDA approval of ARYMO™ ER. Interest on the 13% Notes accrues at a rate of 13% per annum and is payable semi-annually in arrears on each Payment Date, which occurs on March 20 and September 20 of each year which commenced on March 20, 2017. On each Payment Date commencing on March 20, 2018, we will pay an installment of principal on the 13% Notes in an amount equal to 15% (or 17% if certain sales targets are not met) of the aggregate net sales of OXAYDO, SPRIX Nasal Spray, ARYMO ER and Egalet-002, if approved, for the two consecutive fiscal quarter period most recently ended, less the amount of interest paid on the 13% Notes on such Payment Date.

In connection with the Initial Offering in August 2016, we entered into royalty rights agreements with each of the 13% Notes Purchasers pursuant to which we sold to such Purchasers the right to receive, in the aggregate, a payment equal to 1.5% of the aggregate net sales of OXAYDO and SPRIX Nasal Spray from the Initial Closing through December 31, 2019, inclusive (the “Royalty Rights”). Following the approval of ARYMO ER in January 2017, the Royalty Rights will continue through December 31, 2020 and we also entered into separate Royalty Rights agreements with each of the Purchasers pursuant to which we sold to such Purchasers the right to receive 1.5% of the aggregate net sales of ARYMO ER payable from the date of first sale of ARYMO ER through December 31, 2020, inclusive. The above table does not include any potential payments related to the Royalty Rights.

- (3) On April 1, 2015, we issued, through a private placement, \$60.0 million in aggregate principal amount of the 5.50% Notes. On May 6, 2015, we issued an additional \$1.0 million in principal amount pursuant to the initial purchasers’ exercise of their 30-day over-allotment for aggregate gross proceeds of \$61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, which commenced on October 1, 2015.
- (4) On February 28, 2017, we entered into a Drug Product Manufacturing Services Agreement (the “Manufacturing Agreement”) with Halo Pharmaceutical, Inc. (“Halo”) pursuant to which we engaged Halo to provide certain



services related to the manufacture and supply of ARYMO ER tablets for our commercial use in the United States. We are obligated to purchase all of our requirements for ARYMO ER from Halo through 2019, and seventy-five percent of our requirements thereafter, subject to certain limited exceptions. We will purchase ARYMO ER pursuant to binding purchase orders at a fixed price based on dosage strength, with specified percentage rebates for annual volumes of product ordered over a specified amount. In addition, we have agreed to purchase certain minimum amounts of manufacturing and additional services per calendar quarter from Halo over the term of the Agreement (the “Quarterly Minimum”). If we fail to meet the Quarterly Minimum, we will be required to pay to Halo the resulting shortfall.

We have employment agreements with our executive officers that require the funding of a specific level of payments if specified events occur, such as a change in control or termination without cause. However, because of the contingent nature of those payments, they are not presented in the table.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development, commercial and manufacturing activities. We can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments or long-term commitments of cash.

#### ***Purchase Commitments***

Other than described above with respect to the purchase of ARYMO ER, we have no material non-cancelable purchase commitments with service providers as we have generally contracted on a cancelable purchase order basis.

#### ***Employment Agreements***

We have entered into employment agreements with our president and chief executive officer, chief financial officer, chief operating officer, chief commercial officer, chief medical officer, general counsel and senior vice president of research and development, that provide for, among other things, salary, bonus and severance payments.

#### ***Legal Proceedings***

Please refer to Note 11 - “Commitments and Contingencies—Legal Proceedings” in the notes to the unaudited consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

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

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

#### ***JOBS Act***

As an “emerging growth company” under the JOBS Act of 2012, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing not to delay our adoption of such new or revised accounting standards. As a result of this election, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2016 and March 31, 2017, we had cash and cash equivalents and marketable securities of \$86.8 million and \$105.3 million,

respectively, consisting of money market funds, certificates of deposit, U.S. government agency securities and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

We have international operations and as a result, contract with vendors internationally. We may be subject to fluctuations in foreign currency rates in connection with payments made under these agreements. Historically, we have not hedged our foreign currency exchange rate risk, as the impacts of changes in foreign currency rates on payments made under these arrangements have not been material.

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

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

Our management, with the participation of our chief executive officer (“CEO”) and chief financial officer (“CFO”), has evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our management, including our CEO and CFO, concluded that as of March 31, 2017 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

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

During the three months ended March 31, 2017, we implemented a new enterprise resource planning (“ERP”) system. As appropriate, we are modifying the design and documentation of internal control processes and procedures relating to the new system and interfaces to simplify and synchronize our existing internal control over financial reporting.

With the exception of the ERP implementation described above, there were no changes in our internal control over financial reporting during the first quarter of 2017, which were identified in connection with management’s evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II**

### **ITEM 1. LEGAL PROCEEDING S**

Refer to Note 11 - Commitments and Contingencies—Legal Proceedings in the notes to the unaudited consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

### **ITEM 1A. RISK FACTORS**

We are subject to various risks and uncertainties that could have a material impact on our business, financial condition, results of operations and cash flows. The discussion of these risk factors is included in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. There have been no changes to these risk factors during the three months ended March 31, 2017.

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

#### **Recent Sales of Unregistered Securities**

On August 31, 2016, we completed the initial closing (the “Initial Closing”) of our offering (the “Offering”) of up to \$40.0 million aggregate principal amount of our 13% senior secured notes (the “13% Notes”) and entered into an indenture governing the Notes with the guarantors party thereto and U.S. Bank National Association, a national banking association, as trustee and collateral agent. We issued an additional \$40.0 million aggregate principal amount of the 13% Notes following FDA approval of ARYMO ER in January 2017 (the “Second Closing”). The 13% Notes were sold directly only to qualified institutional buyers within the meaning of Rule 144A under the Securities Act in reliance upon the exemption from the registration requirements of the Securities Act pursuant to Section 4(a)(2) thereof relative to transactions by an issuer not involving any public offering. Morgan Stanley & Co., LLC was the placement agent in connection with the sales of the 13% Notes. We received net proceeds from the Initial Closing and Second Closing of approximately \$37.2 million and \$38.3 million, after deducting the offering expenses payable by us.

#### **Issuer Purchases of Equity Securities**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

<b>Exhibit Number</b>	<b>Description</b>
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended (incorporated by reference to Exhibit 3.1 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2015).
3.2	Amended and Restated Bylaws of Egalet Corporation (incorporated by reference to Exhibit 3.2 to Egalet Corporation's current report on Form 8 - K filed with the Securities and Exchange Commission on February 11, 2014).
10.1	Form of Royalty Rights Agreement (incorporated by reference to Exhibit 10.2 to Egalet Corporation's current report on Form 8 - K filed with the Securities and Exchange Commission on January 18, 2017).
10.2*	Drug Product Manufacturing Services Agreement dated as of February 28, 2017 by and among Halo Pharmaceutical, Inc., and Egalet Corporation, Egalet, Ltd, and Egalet US Inc. (filed herewith).
10.3	Egalet Corporation 2017 Inducement Plan (incorporated by reference to Exhibit 10.29 to Egalet Corporation's Annual Report on Form 10 - K filed with the Securities and Exchange Commission on March 13, 2017).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith).
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith).
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document (filed herewith).
101.SCH	XBRL Taxonomy Extension Schema Document (filed herewith).
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).

\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 10, 2017

EGALET CORPORATION

By:                     /s/ ROBERT S. RADIE                      
Robert S. Radie  
*President and Chief Executive Officer*

**EXHIBIT INDEX**

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\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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## **D RUG PRODUCT MANUFACTURING SERVICES AGREEMENT**

**THIS DRUG PRODUCT MANUFACTURING SERVICES AGREEMENT** (this “**Agreement**”) is effective as of February 28, 2017 (the “**Effective Date**”) by and between Halo Pharmaceutical, Inc., a Delaware corporation, having offices at 30 North Jefferson Road, Whippany, NJ 07981 (“**Halo**”), and Egalet Corporation, a Delaware corporation, having offices at 600 East Lee Road Suite 100 Wayne, PA 19087, Egalet, Ltd, a UK company having offices at 160 Queen Victoria Street London EC4V 4QQ and Egalet US Inc., having offices at 600 Lee Road, Wayne, PA 19087 (collectively known as “**Client**”).

### **RECITALS**

A. Client develops, markets and sells pharmaceutical products, including the product(s) generally known as ARYMO™ ER Tablets.

B. Halo provides pharmaceutical product development, manufacturing and packaging services from its facility in New Jersey.

C. Halo and Egalet Ltd., an Affiliate of Client, have executed a Project Management/Services Agreement (“**PMSA**”) dated October 8, 2015.

D. Client desires to engage Halo to provide certain commercial manufacturing and related services to Client, and Halo desires to provide such services, on the terms and subject to the conditions set out below in this Agreement.

**NOW THEREFORE**, the parties agree as follows:

### **ARTICLE 1** **DEFINITIONS**

**1.1 Glossary.** The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

“**API**” means the active pharmaceutical ingredient(s) listed on Schedule G. The parties acknowledge that certain API may be controlled substances under Applicable Laws.

“**API Specifications**” means, with respect to a given API, the specifications for such API, including chemical name, structure, reference profile, limits, impurities, physical properties, identity tests, analytical methods, storage requirements, and similar information, all of which shall be attached to the Quality Agreement.

Halo Pharma • Confidential

[\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

“ **Affiliate** ” of a party means a business entity that directly or indirectly controls, is controlled by, or is under common control with such party, where “ **control** ” means the ownership of shares or other ownership interests or rights carrying at least a majority of the votes in respect of the election of the directors of a corporation or the equivalent managers of any other business form. Egalet Corporation and all its Affiliates, including Egalet, Ltd, and Egalet US, Inc., are jointly and severally liable under this Agreement, and any notice or direction to Halo hereunder from any one of them shall function as notice or direction from all of them, upon which Halo is entitled to rely.

“ **Applicable Laws** ” means all laws, statutes, ordinances, regulations, rules, judgments, decrees or orders of any Authority: (i) with respect to each party, in any jurisdiction in which such party actually operates or performs activities hereunder; (ii) with respect to Client, in any jurisdiction in which API, PEO or Product are produced, marketed, distributed, used or sold; and (iii) with respect to Halo, in any jurisdiction expressly designated in the Specifications. The term Applicable Laws includes cGMPs.

“ **Authority** ” means any governmental authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether international, supranational, federal, state, provincial, county or municipal.

“ **Business Day** ” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the state of New Jersey, United States.

“ **cGMPs** ” means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States Code of Federal Regulations together with any binding FDA guidance documents pertaining to manufacturing and quality control practice, and any equivalent rules governing the manufacture of pharmaceutical products promulgated by any Regulatory Authority of any jurisdiction expressly designated in the Specifications; in each case, as in effect, updated, amended and revised from time to time during the Term.

“ **Commercially Reasonable Efforts** ” means efforts and resources normally used by a party that are consistent with the efforts and resources used by a pharmaceutical or manufacturing company, as the case may be, of similar size and market capitalization as such party in the exercise of its commercially reasonable business practices relating to an exercise of a right or performance of an obligation under this Agreement, including for a compound or product owned by it or to which it has rights, which is of similar stage in its product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable product and other relevant factors.

“ **Components** ” means, collectively, all raw materials, ingredients and packaging (including labels, product inserts and containers), required to be used in order to produce the Products in accordance with the Specifications, other than the API, PEO and Consumables. The term Components includes Exclusive Components.

“ **Conforming Product** ” means Product delivered by Halo hereunder that meets the Product Warranty.



“ **Contract Quarter** ” means the full calendar quarters beginning with January 1, April 1, July 1, and October 1 of each calendar year; *provided* , that (a) the first Contract Quarter shall commence January 1, 2017 and (b) in respect of any period after the end of the last Calendar Quarter but before the expiration or termination date of this Agreement (e.g., if the Agreement terminates on October 31, then the period from October 1 through October 31), any obligation or payment accruing on a Contract Quarter basis (including Quarterly Minimums) shall apply *pro rata* to such period.

“ **DEA** ” means the United States Drug Enforcement Agency or any successor thereto.

“ **FDA** ” means the United States government department known as the Food and Drug Administration or any successor thereto.

“ **Finished Goods** ” means the Product in its final configuration for purposes of this Agreement ( *e.g.* , tablets in bottles with labels and package insert or in bulk form) as described in the Specifications.

“ **Injection Molding Machines** ” or “ **IM Machines** ” means the equipment set forth on Schedule J.

“ **Intellectual Property** ” means all intellectual property and embodiments thereof, including patents, patent applications, trademarks, trademark applications, tradenames, copyrights, industrial designs, trade secrets and Inventions.

“ **Invention** ” means information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable. [\*\*\*\*\*].

“ **Inventory** ” means all inventories of Components, Consumables, Product and work-in-process purchased, produced, held or maintained by Halo as contemplated by Section 2.4(b) or Section 4.3, including any excess material purchased by reason of vendor’s minimum purchase requirements and long lead time material. For the avoidance of doubt, Inventory does not include any API or PEO.

“**Latent Defect**” means any defect that is not normally detected by visual inspection or the analytical methods used to characterize the Product, API or PEO at the time of release.

“ **Manufacturing Services** ” means the manufacturing, quality control, quality assurance and stability testing, packaging (in bulk or finished packaging), labeling and related services, as contemplated in this Agreement, required to produce Products from API, PEO and Components. The term Manufacturing Services excludes Additional Services.

“ **Manufacturing Site** ” means the facility owned and operated by Halo located at 30 North Jefferson Road, Whippany, New Jersey, 07981, USA.

“ **Maximum API Credit Value** ” means the maximum value of API that may be credited by Halo pursuant to this Agreement, as set forth on Schedule G.

“ **Maximum PEO Credit Value** ” means the maximum value of PEO that may be credited by Halo pursuant to this Agreement, as set forth on Schedule G.

“ **Packaging Fee** ” means the per-unit fee for the Packaging of Product payable by Client to Halo and set forth on Schedule A in the column so labeled, as the same may be adjusted in accordance with this Agreement.

“ **PEO** ” means [\*\*\*\*\*].

“ **PEO Specifications** ” means the written specifications for PEO as published by the manufacturer thereof and including limits, impurities, physical properties, identity tests, analytical methods, storage requirements, and similar information, all of which shall be attached to the Quality Agreement.

“ **Person** ” shall mean any individual, corporation, proprietorship, firm, partnership, limited partnership, limited liability company, trust, association or other entity.

“ **Price** ” means the per-unit sale price for Product payable by Client to Halo and set forth on Schedule A in the column so labeled, as the same may be adjusted in accordance with this Agreement.

“ **Product** ” means a pharmaceutical product listed on Schedule A, as more specifically described in the Specifications.

“ **Quality Agreement** ” means an agreement between Halo and Client setting out the quality assurance standards applicable to the Manufacturing Services and the parties’ responsibilities in respect thereof.

“ **Quota** ” shall mean the manufacturing quota quantity of a given API allotted by the DEA to Halo for a given calendar year.

“ **Recall** ” means any action (i) by Client to recover title to or possession of quantities of Product sold or shipped to Third Parties and to remove that Product from its physical location at a Third Party’s location (including any voluntary withdrawal of Product from the market), (ii) by Client to modify, adjust, relabel, destroy, or inspect (including through patient monitoring) Product sold or shipped to Third Parties without recovering title or possession, or (iii) by any Regulatory Authority to recall, withdraw from the market, order any corrective action, or otherwise detain or destroy any of the Product.

“ **Regulatory Approval** ” means permission, authority, or approval from a Regulatory Authority to permit marketing and/or sale of a Product, including, but not limited to, investigational new drug applications, new drug applications, abbreviated new drug applications, and biologics license applications

“ **Regulatory Authority** ” means any Authority competent to grant marketing, distribution and related approvals for pharmaceutical products in the Territory and in the jurisdictions in which the Manufacturing Sites are located, including the FDA and DEA, as applicable.

“ **Specifications** ” means, with respect to a Product, the following written information, which are included in Schedule A and/or which shall be attached to the Quality Agreement and/or which Client shall provide to Halo (and may subsequently revise) in accordance with Section 3.3: [\*\*\*\*\*].

“ **Territory** ” means the geographic area specified in Schedule I where the Product is to be offered for sale by Client or its Affiliates or licensees.

“ **Third Party** ” shall mean any Person other than Halo, Client and their respective Affiliates.

“ **Third Party Rights** ” means the rights held by a Third Party in Intellectual Property.

“ **Year** ” means, (i) with respect to the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same year, (ii) with respect to the last year of this Agreement, the period from January 1 of such last calendar year up to and including the date of termination or expiration of this Agreement, and (iii) for all periods in between, a calendar year.

**1.2 Index.** The following terms are defined in the section of this Agreement indicated below:

<b>Term</b>	<b>Section</b>
Actual Annual Yield or AAY	2.3(c)
Additional Services	2.2(a)
Agreement	Introductory paragraph
API Cost	2.1(b)(i)
Broader Intellectual Property Rights	12.2(b)
Client	Introductory paragraph
Client Indemnitees	10.3(a)
Client Party	13.1
CMC	7.7(c)
Commitment	3.2(b)
Confidential Information	11.1
Consumables	2.1(b)(iv)
Contributing Expenses	4.2(b)
Deficiency Notice	6.1(a)
Dispute	13.1
Effective Date	Introductory paragraph
Exclusive Components	4.3(b)
Exclusive Components Purchasing Summary	4.3(b)

Facilitator	13.1
Firm Order	4.1(b)
Force Majeure Event	14.1
Forecast (including Forecasted)	3.2(a)
Forfeit Date	4.2(d)
Halo	Introductory paragraph
Halo Indemnitees	10.3(b)
Initial Term	8.1
Losses	10.3(a)
Machine Space	2.1(b)(vi)(B)
Master Confidentiality Agreement	11.1
Materials Credit	2.3(e)
Non-Compliant Services	6.3(a)
Non-Conforming Product	6.1(a)
Packaging	3.5
PEO Cost	2.1(b)(ii)
PMSA	Recital C
Product Warranty	9.3(e)
Proposed Response	7.5
Purchase Order	4.1(a)
Quantity Converted	2.3(a)
Quantity Dispensed	2.3(a)
Quantity Received	2.3(a)
Quarterly Minimum	4.2(a)
Reconciliation Report	2.3(d)
Records	7.3
Renewal Term	8.1
Requirements Obligation	2.1(a)
Shortfall	2.3(d)
Supply Shortage	2.4(a)
Target Yield	2.3(b)
Target Yield Determination Batches	2.3(b)
Technical Dispute	13.2
Term	8.1
Third Party Claim	10.3(a)
True Up Amount	4.2(c)

## ARTICLE 2 HALO's services

## 2.1 Manufacturing Services

(a) Arrangement. In consideration of Client's payment of the fees due under, and the other terms and conditions of, this Agreement, Halo shall perform the Manufacturing Services at the Manufacturing Site in order to supply Product to Client for sale in the Territory. Client shall purchase (i) one hundred percent (100%) of its requirements for Product in calendar years 2017, 2018 and 2019, and (ii) seventy-five percent (75%) of its requirements for Product in each calendar year during the Term thereafter (" **Requirements Obligation** ") from Halo except to the extent otherwise expressly permitted in this Agreement. Halo acknowledges that Client may take any commercially reasonable steps necessary to protect its supply of Product, including by establishing a backup source of supply for Product and/or manufacturing Product itself or purchasing Product from Third Parties; in each case subject to the Requirements Obligation. However, the Requirements Obligation shall not apply and shall be waived solely for [\*\*\*\*\*].

(b) Conversion of API, PEO and Components. Halo shall convert API, PEO and Components into Finished Goods in accordance with this Agreement.

(i) API. Client shall purchase at its sole cost and expense all API, and deliver API to Halo in accordance with Section 3.4. Halo shall visually inspect API upon receipt to verify identity and quantity and shall test each shipment of API in accordance with the Quality Agreement. Halo shall store such API on behalf of the Client on the terms and subject to the conditions hereof. The parties acknowledge and agree that title to API shall at all times belong to and remain the property of the Client. Except as set forth in this Agreement, risk of loss of the API shall at all times remain with Client. Client will insure the API at Client's cost. Halo agrees that any API received by it from or on behalf of Client shall (A) only be used by Halo to provide the Manufacturing Services, (B) be stored and handled in accordance with the API Specifications, any special instructions agreed between Client and Halo in writing, and Applicable Law, and (C) be kept free of all liens, claims and encumbrances arising from acts or omissions of Halo. Halo shall notify Client promptly of any material damage to or destruction of API, and shall compensate Client for any API lost, destroyed or damaged during Halo's storage of API due to Halo's negligence, wilful misconduct or breach of this Agreement at an amount equal to [\*\*\*\*\*] (" **API Cost** "), subject to the Maximum API Credit Value; *provided* , that for ease of administration, in lieu of calculating the actual API Cost, the parties have agreed and set forth on Schedule G a number that represents and will be used as the API Cost ([\*\*\*\*\*]). For the avoidance of doubt, Client shall be compensated for any other API lost, destroyed or damaged during Halo's manufacture of Product as follows: (1) to the extent included in Conforming Product and exceeding the Target Yield, through the mechanism set forth in Section 2.3 and (2) to the extent included in Nonconforming Product, through the mechanism set forth in Article 6.

(ii) PEO. Client shall purchase at its sole cost and expense all PEO, and deliver PEO to Halo in accordance with Section 3.4. Halo shall visually inspect PEO upon receipt to verify identity and quantity and shall test each shipment of PEO in accordance with the Quality Agreement. Halo shall store such PEO on behalf of the Client on the terms and subject to the conditions hereof. The parties acknowledge and agree that title to PEO shall at all times belong to and remain the property of the Client. Except as set forth in this Agreement, risk of loss of the PEO shall at all times remain with Client. Client will insure the PEO at Client's cost. Halo agrees

that any PEO received by it from or on behalf of Client shall (A) only be used by Halo to provide the Manufacturing Services, (B) be stored and handled in accordance with the PEO Specifications, any special instructions agreed between Client and Halo in writing, and Applicable Law, and (C) be kept free of all liens, claims and encumbrances arising from acts or omissions of Halo. Halo shall notify Client promptly of any material damage to or destruction of PEO, and shall compensate Client for any PEO lost, destroyed or damaged during Halo's storage of PEO due to Halo's negligence, wilful misconduct or breach of this Agreement at an amount equal to [\*\*\*\*\*] (" **PEO Cost** "), subject to the Maximum PEO Credit Value; *provided* , that for ease of administration, in lieu of calculating the actual PEO Cost, the parties have agreed and set forth on Schedule G a number that represents and will be used as the PEO Cost ([\*\*\*\*\*]). For the avoidance of doubt, Client shall be compensated for any other PEO lost, destroyed or damaged during Halo's manufacture of Product as follows: (1) to the extent included in Conforming Product and exceeding the Target Yield, through the mechanism set forth in Section 2.3 and (2) to the extent included in Nonconforming Product, through the mechanism set forth in Article 6.

(iii) Components . Halo shall purchase all Components as required by and included in the Specifications and as further described in Section 4.3. Halo shall procure only Components that are warranted by the vendor to have been manufactured in accordance with cGMPs. Halo shall test all Components after receipt at the Manufacturing Site as required by the Specifications and the Quality Agreement.

(iv) Consumables . Halo shall purchase all columns and standards, and subject to Client's prior written approval for purchases exceeding [\*\*\*\*\*], tooling and other project-specific items, necessary for Halo to perform the Manufacturing Services (" **Consumables** "). Halo shall charge through to Client all Third Party vendor fees for such purchases at Halo's actual cost [\*\*\*\*\*].

(v) Credit . Any Components or Consumables previously purchased by Halo and paid for by Client under any purchase order prior to the Effective Date and used in the Manufacturing Services shall not be invoiced or charged-through, including any administrative fees, to Client.

(vi) Equipment .

(A) General . Except as Halo and Client may agree in writing from time to time, Halo shall provide at its cost all equipment needed to perform the Manufacturing Services, with the exception of the Client-owned Injection Molding Machines and associated parts. Client has installed the IM Machines at the Manufacturing Site pursuant to the PMSA and, subject to the rights of Client's Third Party lien-holders, and subject to the terms of this Agreement (including without limitation clauses (D) and (E) below and Section 4.2(d)), Halo shall have the right of possession and control of the IM Machines at all times during the Term . Client shall carry appropriate insurance on the IM Machines at all times during the Term . Halo shall use the IM Machines and associated parts solely for the benefit of Client, and may not use such equipment for any other purpose or customer, unless otherwise approved in writing by Client following a request from Halo. Title to all IM Machines will remain solely with Client.

(B) Machine Space. Halo agrees that the area at the Manufacturing Site in which the IM Machines have been installed and certain adjoining space, all as more specifically described on Schedule B (the “ **Machine Space** ”), shall remain dedicated to the IM Machines during the Term, subject to the terms and conditions of this Agreement, including this Section 2.1(b)(vi) and Section 4.2(d). In consideration of Halo making the Machine Space available to Client (which shall be considered an Additional Service under this Agreement), Client shall pay the IM Machine space fee set forth on Schedule B; *provided*, that Halo shall waive such fee, and such fee shall not be payable by Client, for each Contract Quarter in which Client fulfills the Quarterly Minimum (as reduced or waived pursuant to Sections 4.2(a), 4.2(d) or 8.2(a)), whether by purchasing Product or Contributing Services or making payments in lieu thereof. Client agrees and acknowledges that the availability of the Machine Space hereunder for the IM Machines is for the parties’ convenience in connection with ensuring Halo’s ability to supply Product hereunder, and is not and shall not be deemed a lease, rental or other interest in real property, and agrees that Client is not and shall not be deemed, and shall not be entitled to any of the rights afforded to, a lessee under applicable law, including but not limited to any right of entry, possession or quiet enjoyment.

(C) Maintenance. Halo will perform and be responsible for the costs and expenses of routine maintenance and servicing of [\*\*\*\*] IM Machine while located at the Manufacturing Site. Halo will perform routine maintenance and servicing on all additional IM Machines while located at the Manufacturing Site at Client’s expense at [\*\*\*\*]. Client will perform and be responsible for the cost of non-routine maintenance and servicing of the IM Machines (such as major repairs and parts replacement), except where such non-routine maintenance or servicing results from Halo’s failure to operate, maintain and service the IM Machines in accordance with the vendor’s instructions or from Halo’s negligence or willful misconduct. Halo will promptly notify Client of the need for any such non-routine maintenance or servicing. Further, Halo will permit at all times during normal working hours Client and its personnel and agents, and the manufacturers of the IM Machines, to have access to the IM Machines in order to perform maintenance and servicing.

(D) Termination of Agreement. Upon the expiration or termination of this Agreement or in connection with a Client request under Section 4.2(d), Halo shall surrender possession of the IM Machines to Client in the same order, condition and repair as received, ordinary wear and tear excepted, at the Manufacturing Site. Client shall complete the removal of the IM Machines within [\*\*\*\*] following the expiration or termination of this Agreement or the Forfeit Date, as applicable. If and to the extent Client fails to remove the IM Machines within such [\*\*\*\*] period, Halo may uninstall the IM Machines and transfer them to storage, and Client shall pay rent at the rate set forth on Schedule B, as well as all maintenance and other costs pursuant to clause (A) above. Halo shall invoice Client for such amounts due monthly in arrears. Upon removal of any IM Machines, unless such removal occurs due to termination of this Agreement for Halo’s material breach or insolvency, Client shall, at its sole cost and expense, return the Manufacturing Site (or the forfeited suite under Section 4.2(d)) and its systems to a condition reasonably suitable for cGMP manufacturing, except as may otherwise be agreed in writing by Halo.



(E) Issues Arising from IM Machines. Notwithstanding anything to the contrary in this Agreement, the Quality Agreement, or otherwise, so long as Halo shall have operated, maintained and serviced the IM Machines in accordance with the vendor's instructions and, so long as not inconsistent with the vendor's instructions and subject to clause (C) above, Client's instructions, Halo shall have no liability in connection with any issue, problem or other matter whatsoever to the extent arising from any of the IM Machines, including without limitation any failure to supply Product, delay in Product supply, Supply Shortage, Non-Conforming Product, need for rework or reprocessing, loss of API, PEO, Components and/or Packaging, failure to achieve Target Yield, Recall, scrap, etc.; and Halo shall be entitled to receive the Price, Packaging Fee and/or other amounts hereunder for work performed even if any such issue, problem or other matter occurs, except to the extent that the relevant issue, problem or other matter whatsoever arising from any of the IM Machines results from any Halo external physical machinery, Halo building infrastructure, Halo processes, or Halo equipment that adversely affects operation of the IM Machines or similar Halo negligence or willful misconduct unrelated to the IM Machines.

(vii) Batch Number and Expiration Date. Halo will assign each batch of Product manufactured by it assigned a unique batch number using Halo's batch numbering system. This batch number will appear on all documents relating to the particular batch of Product. Halo will calculate the expiration date for each batch of Product based on the date of compounding such batch.

(c) Packaging. Halo shall package Product as required by the applicable Firm Order. Halo shall be responsible for imprinting or affixing the batch number and expiration date of each batch of Product onto the Finished Goods and shipping cartons as described in the Specifications and required by the Quality Agreement and cGMPs and, when required by the Drug Safety Control & Security Act, a serial number and 2D barcode. Halo's name shall not appear on any Product Packaging except to the extent (i) required by any Applicable Laws or (ii) Halo expressly consents in writing to such use of its name.

(d) Quality Control. Halo shall perform the Product quality control and quality assurance testing required by the Quality Agreement. Product batch review and release to Client shall be the responsibility of Halo's quality assurance group. Halo shall perform such batch review and release responsibilities in accordance with Halo's standard operating procedures. Unless prevented by deviations or failures, or agreed to in writing by Client, Halo will complete its batch review within [\*\*\*\*\*] following completion of Product production. Each time Halo delivers a batch of Product to Client, Halo shall provide Client with a certificate of analysis and certificate of compliance for such batch. At Client's request, Halo will provide copies of additional batch documentation, including, but not limited to batch manufacturing records, lot packaging records, equipment data printouts, raw material data, and laboratory notebooks, at no additional cost for one copy.

## **2.2 Additional Services**

(a) Product Related Services. In addition to the Manufacturing Services, Halo shall perform any services in connection with Product as Halo and Client may agree in writing from



time to time, such as qualification, validation, and stability services ( including as contemplated by Section 2.2(b), “ **Additional Services** ”) . Such written agreement shall specify the scope, timing, parameters (including protocols, if applicable), fees payable by Client, and other matters pertinent to the Additional Services. To the extent Halo and Client have agreed any such matters as of the Effective Date, they are set forth on Schedule B. The terms and conditions of this Agreement shall govern the provision and receipt of any Additional Services. Schedule K is a complete and accurate list of all current Additional Services that are being performed by Halo as of the Effective Date, and are evidenced by Halo work orders and Egalet Purchase Orders.

(b) Post Marketing Stability Testing. At Client’s request, in consideration of the fees set forth on Schedule B, Halo shall conduct post marketing stability testing on Product in accordance with such commercial and Product stability protocols as Halo and Client may agree in writing. Halo shall not make any changes to these protocols without Client’s prior written consent, which shall not be unreasonably withheld, conditioned or delayed. In the event of a confirmed stability test failure, Halo will notify Client within [\*\*\*\*\*] of such confirmation. Halo and Client shall cooperate to determine the proceedings and methods to be undertaken to investigate the causes of such failure, including the allocation between Halo and Client of the cost of such investigation. To the extent Client pays for all or part of the investigation, Halo’s costs will be billed to Client at the rate set forth on Schedule B. Each investigation must give rise to an explanation and/or corrective action, which shall be reviewed by Halo’s quality assurance department. Upon Client’s request, Halo will provide Client with a copy of all data and results relating to any post marketing stability testing and/or any such investigation. If required by Applicable Law, Client is responsible to, and shall, file a field alert or other required notice with the FDA.

## **2.3            Yield**

(a) Interim Inventory Reports. The Manufacturing Site shall provide Client with monthly and quarterly inventory reports for each API and PEO held by Halo. Each inventory report shall be in substantially the form set forth on Schedule C, shall be based on data from Halo’s manufacturing resource planning (MRP) system and/or manufacturing batch records, and shall contain the following information with respect to the applicable period:

(i) “ **Quantity Received** ”: The total quantity labeled on drums of API/PEO received at the Manufacturing Site that comply with the Specifications, less any incoming samples, retains or quantities used for testing purposes (such as stability samples);

(ii) “ **Quantity Dispensed** ”: The total quantity of API/PEO dispensed from inventory at the Manufacturing Site in connection with commercial manufacturing of Product, less any (A) API/PEO that must be retained by Halo as samples and stability, (B) API/PEO contained in Product that must be retained as samples, (C) API/PEO used in connection with testing (if applicable) and (D) API/PEO received or consumed in connection with technical transfer activities or development activities, including any regulatory, stability, validation, or test batches manufactured; and

(iii) “ **Quantity Converted** ”: The total amount of API/PEO contained in Product produced with the Quantity Dispensed (including any replacement Product produced in accordance with Article 6), which Product was delivered by Halo and not rejected, Recalled or returned in accordance with Article 6 as a result of Non-Compliant Services, less any API/PEO losses due to sampling (including retain), testing or stability.

(b) Target Yield. For each batch size of Product, after Halo has produced [\*\*\*\*\*] (collectively, the “ **Target Yield Determination Batches** ”) pursuant to this Agreement, Halo and Client will agree on the target yield for the API and PEO used in such Product at the Manufacturing Site for such batch size (each, a “ **Target Yield** ”); *provided*, that the Target Yield Determination Batches shall not include any batches that were produced in production runs involving technical difficulties or involving an extraordinary loss of API or PEO, as agreed by both Halo and Client.

(c) Actual Annual Yield and Report. Within [\*\*\*\*\*] after the end of each Year, Halo shall prepare for each API and PEO used in a Product an annual reconciliation report substantially in the form attached as Schedule D (the “ **Reconciliation Report** ”), including the calculation of the “ **Actual Annual Yield** ” or “ **AA Y** ” for such API or PEO used in such Product at each Manufacturing Site for all batch sizes during the Year, expressed as a percentage of Quantity Dispensed and calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}}$$

(d) Shortfall Calculation. If the Actual Annual Yield falls more than [\*\*\*\*\*] below the Target Yield for a given Year, then the shortfall for such Year (the “ **Shortfall** ”) shall be determined based on the following calculation:

[\*\*\*\*\*]

Any Shortfall shall be disclosed by Halo on the Reconciliation Report and Halo will undertake an investigation of the reasons for the Shortfall.

(e) Materials Credit. If there is a Shortfall for any API or PEO for a given Year, Halo shall credit Client’s account for the amount of such Shortfall within [\*\*\*\*\*] after the end of such Year, up to a maximum aggregate credit amount equal to the Maximum API Credit Value in respect of API and the Maximum PEO Credit Value in respect of PEO (the amount of such Shortfall for API or PEO, as capped by the Maximum API Credit Value or Maximum PEO Credit Value, as applicable, the “ **Materials Credit** ”). Each Materials Credit shall be summarized on the Reconciliation Report and shall be used to offset amounts owed to Halo under invoices issued to Client in accordance with Section 5.6. Upon expiration or termination of this Agreement, Halo shall pay Client an amount equal to any remaining Materials Credit ( *i.e.*, that was not used to offset invoices issued to Client) within [\*\*\*\*\*] following the date of such expiration or termination.

(f) No Material Breach. It shall not constitute a material breach of this Agreement by Halo, for the purposes of Section 8.2(a), if the Actual Annual Yield is less than the Target Yield.

## **2.4                    Supply Shortages and Safety Supplies.**

(a)     Supply Shortage.    A “ **Supply Shortage** ” shall be deemed to have taken place if quantities of Conforming Product supplied by Halo to Client are either [\*\*\*\*\*]. A Supply Shortage shall be considered a material breach of this Agreement, but such breach shall be deemed cured upon tender of delivery by Halo of Conforming Product within the applicable cure period.

(b)     Safety Supplies.    Halo shall maintain an inventory of API (subject to Quotas), PEO and Components that would reasonably be expected to suffice for Halo to meet Client’s then-current Forecast. At Client’s request, Halo shall also maintain an inventory of Finished Goods as specified by Client. Halo shall turn over all such safety supplies as new API, PEO and Components are received or new lots of Product are delivered, respectively, to optimize the shelf life of such safety supplies. Halo shall promptly notify Client in writing at any time if it reasonably anticipates that additional amounts of API or PEO will be needed for Halo to meet Client’s then-current Forecast. If Halo reasonably believes that it is or will be unable to obtain a sufficient supply of Components from Third Party vendors for Halo to meet Client’s then-current Forecast, Halo shall promptly notify Client in writing and Client shall have the right to negotiate directly with such Third Party vendors to secure an adequate supply of such Components. If Client directs Halo to maintain Finished Goods in inventory pursuant to this Section 2.4(b) and fails to take possession of such Finished Goods within [\*\*\*\*\*] following its release, Client shall pay Halo the monthly storage fee set forth in Schedule B thereafter for storing such Product. Upon [\*\*\*\*\*] written notice to Client, Halo shall have the option to ship to Client at Client’s expense any finished Product, Components, API and PEO held by Halo in inventory hereunder longer than [\*\*\*\*\*].

## **2.5                    Quotas.**

(a)     Quota Request Filings.    The parties acknowledge that certain API hereunder is scheduled under the Federal Controlled Substances Act, and that Halo is required to obtain a Quota from DEA before manufacturing a Product. Halo will submit to DEA in a reasonably timely manner all documents required by the DEA to request a Quota sufficient to meet Client’s Forecasts made pursuant to Article 3.2; *provided* , that Client shall submit, in a reasonably timely manner, to Halo proposed documentation (including justification of quantities requested by Client) to be included in Halo’s Quota request to DEA. Additional request(s) will be submitted by Halo to DEA in a reasonably timely manner as necessary to reflect changes in Client’s Forecasts, subject again to Halo’s receipt of any necessary supporting documentation from Client.

(b)     Cooperation.    In the event the DEA requires additional information (including, but not limited to, purchase orders) in order to grant a sufficient Quota, Client and Halo agree to cooperate in good faith to obtain such Quota to enable manufacture of the Product. If Halo has notified Client of a shortfall in Quota, Client shall not issue Purchase Orders for a Product in excess of the DEA-approved Quota without Halo’s consent. Halo and Client shall meet to discuss and agree in good faith on adjustments to the Forecast and/or Purchase Orders as a result of the DEA-approved Quota for a Product.

**2.6                    Permits.**    Halo shall at its own cost obtain on a timely basis and maintain all licenses, permits and approvals of Authorities, and make any required filings with Regulatory

Authorities as further specified in Section 7.7, in respect of the operation of Halo's business generally, the Manufacturing Sites, and the performance of services of the nature of the Manufacturing Services; *provided*, that Halo shall have the right to pass through to Client its *pro rata* share of (a) any applicable fees payable by Halo to any Regulatory Authority and (b) reasonable similar fees imposed on the pharmaceutical industry by Regulatory Authorities after the Effective Date, in each case to the extent specifically related to the production of the Product and not to the operation of Halo's business generally or the Manufacturing Sites generally.

### **ARTICLE 3**

#### **CLIENT OBLIGATIONS**

**3.1            Payment.** Client shall pay Halo the fees set forth on Schedule A for the provision of Manufacturing Services (including the Price, Packaging Fee (if applicable), and the annual product review fee) and all other amounts owing pursuant to this Agreement (including in respect of Additional Services, Components, and Consumables), as specified in this Agreement.

**3.2            Rolling Forecasts.**

(a)    Procedure. Concurrently with the execution of this Agreement, Client shall provide Halo with a written [\*\*\*\*\*] forecast of the volume of each Product that Client anticipates it will require Halo to supply during each [\*\*\*\*\*] of that [\*\*\*\*\*] period and indicating the percentage of such Product that will require Packaging (the "**Forecast**"). Client shall provide Halo with an updated Forecast (i) on or before the tenth (10<sup>th</sup>) day of each calendar month on a [\*\*\*\*\*] basis and (ii) promptly following any determination by Client that the volumes set forth in the Forecast most recently provided to Halo have changed [\*\*\*\*\*] or more.

(b)    Binding Portion: Orders. The first [\*\*\*\*\*] of each Forecast shall be binding on Client with respect to the quantities and Packaging presentations of Product specified therein (the "**Commitment**"), and the balance shall be a non-binding, good faith estimate. Client shall place orders for Manufacturing Services against the Forecast as specified in Article 4.

(c)    Capacity Constraints. Notwithstanding anything to the contrary in this Agreement, the parties acknowledge that Halo's capacity to manufacture Product at the Manufacturing Site using the IM Machines [\*\*\*\*\*]. Accordingly, unless and until Product manufacturing [\*\*\*\*\*] is validated and/or the parties successfully introduce and validate a manufacturing process involving [\*\*\*\*\*], in no event shall Client's Forecasts or orders exceed the foregoing capacity. Following validation of manufacturing [\*\*\*\*\*] and following validation of a manufacturing process involving [\*\*\*\*\*], the parties shall discuss in good faith an increase to Client's maximum Forecast and order quantities based on Halo's capacity at the Manufacturing Site using the IM Machines.

**3.3            Specifications.** Prior to the Effective Date, Client has provided Halo with a preliminary copy of certain of the Specifications pertaining to Product. Prior to Client placing its first Firm Order, Client shall provide Halo with originally executed copies of final Specifications (it being understood that any change from the preliminary Specifications shall be subject to the following sentence) and other Product-related information reasonably requested by Halo in connection with the Manufacturing Services. Client may revise the Specifications from time to

time, so long as (i) Client provides Halo with originally executed copies of such revised Specifications, (ii) Halo and Client have complied with Section 5.4, and (iii) Halo and Client have agreed on a timeline for Halo's implementation of such change.

**3.4 Client-Supplied Materials.** Client shall, at its sole cost and expense, deliver the API and PEO to Halo DDP (Incoterms 2010) the Manufacturing Site in sufficient quantities and at such times as to enable Halo to timely provide the Manufacturing Services on a non-rush basis. To this end, Client shall use Commercially Reasonable Efforts to deliver the API and PEO on or about [\*\*\*\*\*] in advance of the date on which Product is scheduled to begin processing, which scheduled processing shall be communicated by Halo to Client in writing. Halo shall have the right to charge Client a storage fee as set forth on Schedule B for API or PEO delivered sooner than [\*\*\*\*\*] in advance of the date on which Product is scheduled to begin processing.

**3.5 Packaging.** Client shall be solely responsible for the development of all artwork and labeling in connection with Product finished packaging, including all associated content and intellectual property matters. Halo shall provide copies of final labeling layouts for Client approval, which Client shall approve or provide comments on within [\*\*\*\*\*] of receipt. Notwithstanding anything to the contrary in this Agreement, if Client fails to timely approve the product labeling and as a result Halo is unable to package Product, Halo shall not be liable for any delay in delivery hereunder, and no supply failure, Supply Shortage, material breach, or similar malfeasance on the part of Halo shall be deemed to have occurred. Client may, in its sole discretion and at its cost, make changes to Product finished packaging, including labels, inserts and cartons ("Packaging") and Client may also request multi-country Packaging as specified in Section 5.5; *provided*, that (i) Client shall be responsible for the cost of all obsolete Components held by Halo when any such Packaging changes occur to the extent Halo procured such Components consistent with Client's then-current Forecast and the vendor's minimum purchase requirements and (ii) Client shall reimburse Halo for all pre-approved, documented costs incurred by Halo (A) in making modifications to Packaging or the imprinting thereof, (B) in connection with changes to any manufacturing processes to accommodate Client's new Packaging, and/or (C) to accommodate any other Packaging changes requested by Client. Upon receipt of any request for modified Packaging, Halo shall use its Commercially Reasonable Efforts to implement such new Packaging in accordance with Client's requested schedule thereof. Client shall provide Halo with any modifications to Packaging as far in advance as possible in order to ensure compliance with Applicable Laws. When requesting reimbursement of any of the foregoing costs, Halo shall invoice Client and provide reasonable supporting documentation thereof. Client shall pay such invoices within [\*\*\*\*\*] after Client's receipt thereof. Notwithstanding anything to the contrary, unless Egalet agrees to pay for the cost of any such changes or capital expenditures and such changes or capital expenditures do not cause a material disruption to Halo's ability to perform services for its other customers, Halo shall not be obligated to make any changes to the Manufacturing Site or incur any capital expenditures to accommodate any Client request for modified Packaging, and Halo may refuse any request for modified Packaging to such extent.

**3.6 Quality Control.** Client shall have sole responsibility for the release of Product to the market and for handling customer matters as contemplated by Section 6.5.

**3.7**            **Permits**. Client shall at its own cost obtain on a timely basis and maintain all licenses, permits and approvals of Authorities, and make any required filings with Regulatory Authorities as further specified in Section 7.7, in respect of the operation of Client's business generally, the Products and the Specifications, including, without limitation, all marketing and post-marketing approvals.

## **ARTICLE 4**

### **ORDERS, authorization to procure, SHIPMENT**

#### **4.1**            **Orders.**

(a)        **Purchase Orders**. From time to time as provided in this Section 4.1(a), Client shall submit to Halo a binding, non-cancellable purchase order for Manufacturing Services identifying an order number, the Product to be manufactured, the number of batches, the batch size (to the extent the Specifications permit batches of different sizes), Client's requested delivery date for each batch, any Packaging (including quantities to be Packaged; it being understood that any Product for which Packaging is not ordered will be bulk packaged), and any other elements necessary to ensure the timely production and delivery of Product (each, a "**Purchase Order**"). Concurrently with the submission of each Forecast, Client shall submit a Purchase Order for all portions of the Commitment not already ordered. Purchase Orders for quantities of Product or Packaging in excess of the Commitment shall be submitted by Client at least [\*\*\*\*\*] in advance of the delivery date requested in the Purchase Order.

(b)        **Firm Orders**. Subject to this Section 4.1(b) and Section 4.1(c) below, Halo will accept in writing each Purchase Order, including the Product, quantity, Packaging and expected delivery date, within [\*\*\*\*\*] of receipt. If Halo has not accepted or rejected a Purchase Order within [\*\*\*\*\*] of receipt, such Purchase Order shall be deemed to be accepted by Halo. If Halo is unable to meet the delivery date requested by Client in its Purchase Order, Halo shall so notify Client in Halo's acceptance of such Purchase Order and provide to Client an alternative delivery date, which shall not be more than [\*\*\*\*\*] earlier or later than the initial delivery date requested by Client in its Purchase Order. Only upon Halo's acceptance of Client-issued Purchase Orders and confirmation of a delivery date will such orders become firm (each, a "**Firm Order**"). Halo may change the expected delivery date of any Firm Order within a [\*\*\*\*\*] window upon written notice to Client (and without Client's prior approval). Halo may not change the quantity of Product in any Firm Order except with Client's prior written approval; *provided*, that Client shall accept any minor change in quantity delivered due to normal yield variation. Client may not change the quantity of Product in any Firm Order; *provided*, that Client may cancel any Firm Order without penalty or other liability if (i) Halo is unable to meet the delivery date requested by Client in its Firm Order [\*\*\*\*\*] or (ii) a Supply Shortage then exists.

(c)        **Rejection; Excess Volume**. Halo may reject any Purchase Order without penalty or liability to Client (i) for Product quantities or Packaging in excess of the Commitment or Halo's capacity constraints described in Section 3.2(c), (ii) if Halo has been granted a Quota for API by the DEA that is insufficient to meet such Purchase Order, or (iii) the Purchase Order is not given in accordance with this Agreement; *provided*, that with respect to clauses (i) and (ii), Halo may reject only the quantity of Product that Halo is unable to supply due to the circumstances described



in such clause (i) or (ii). Notwithstanding the foregoing, Halo shall use Commercially Reasonable Efforts to supply Client with quantities of Product and Packaging that are up to [\*\*\*\*\*] of Commitment quantities, subject to Halo's other supply commitments and manufacturing, packaging and equipment capacity (including as described in Section 3.2(c)).

#### **4.2 Minimum Spend.**

(a) Quarterly Minimum. For the first Contract Quarter (i.e., beginning January 1, 2017), Client shall purchase from Halo and/or its Affiliates an aggregate of [\*\*\*\*\*] : for the second Contract Quarter, Client shall purchase from Halo and/or its Affiliates an aggregate of at least [\*\*\*\*\*] worth of services; for the third Contract Quarter, Client shall purchase from Halo and/or its Affiliates an aggregate of at least [\*\*\*\*\*] worth of services; for the fourth Contract Quarter, Client shall purchase from Halo and/or its Affiliates an aggregate of at least [\*\*\*\*\*] worth of services; and for each Contract Quarter thereafter, Client shall purchase from Halo and/or its Affiliates an aggregate of at least [\*\*\*\*\*] worth of services (such quarterly amount, the “ **Quarterly Minimum** ”). Notwithstanding the foregoing, [\*\*\*\*\*] .

(b) Contributing Services. Services contributing to the fulfillment of the Quarterly Minimum may include (i) Manufacturing Services ( i.e. , for Products and/or additional products added pursuant to Section 14.2) and/or Additional Services under this Agreement and/or (ii) products or services (such as [\*\*\*\*\*] ) under other written agreements between Halo and/or any of its Affiliates, on the one hand, and any Client entity and/or any of its Affiliates, on the other hand. Amounts payable to Halo for such services contributing to the fulfillment of the Quarterly Minimum (e.g., Price and Packaging Fees under this Agreement) are collectively referred to as “ **Contributing Expenses** ”. Contributing Expenses shall exclude (A) pass-through costs, such as in respect of Consumables and Regulatory fees (but shall include any administrative charges assessed by Halo and/or its Affiliates on such pass-through costs), (B) amounts due from or on behalf of Client in connection with indemnity obligations, (C) amounts due from or on behalf of Client in consideration of assets, equity interests, profit shares, or similar investments, and (D) any amounts due from or on behalf of Client other than pursuant to invoices issued by Halo and/or any of its Affiliates for services rendered in the ordinary course of business. Such excluded expenses shall be invoiced and paid in accordance with this Agreement or the other applicable agreement(s) between Halo and Client and/or their respective Affiliates.

(c) True-up. Within [\*\*\*\*\*] after the end of each Contract Quarter, Halo will compare the total amount of the Contributing Expenses invoiced by Halo during the Contract Quarter against the Quarterly Minimum for the same quarter. If the total amount of the Contributing Expenses is less than the Quarterly Minimum, then, except as provided in the next sentence with respect to [\*\*\*\*\*], Halo shall invoice Client for the difference between the Quarterly Minimum and the Contributing Expenses (such difference, a “ **True Up Amount** ”). With respect to [\*\*\*\*\*], the True Up Amount shall not be determined on a Contract Quarter basis and instead shall be determined [\*\*\*\*\*]. If, subsequent to Halo's calculation of the True Up Amount for a given Contract Quarter (or, with respect to [\*\*\*\*\*]), Client successfully disputes all or any part of a Halo invoice issued during such quarter (or for [\*\*\*\*\*]) or if a Halo invoice issued during such quarter (or for [\*\*\*\*\*]) is otherwise reduced, Halo shall have the right to review the Contributing Expenses and the Quarterly Minimum for such Contract Quarter (or [\*\*\*\*\*]). To the extent Halo

would have been entitled to a greater True Up Amount had the invoice originally been issued for the reduced amount, then Halo shall be entitled to invoice Client for such incremental True Up Amount. Additionally, to the extent Client successfully disputes Halo's calculation of the True Up Amount and that results in a lower True Up Amount, then Halo promptly shall refund to Client any overpayment by Client of the True Up Amount.

(d) Reduction in Quarterly Minimums. The Parties agree to use their respective commercially reasonable best efforts to cease the dedication of the Machine Space referred to as the IMS1 and for Client to vacate the IMS1 space as soon as reasonably practicable, but in no event without the written consent of Client relinquishing such IMS1 Machine Space to Halo. Once vacated (the "**Forfeit Date**"), the Quarterly Minimum (and, for the avoidance of doubt, the total monthly Additional Service fee payable under Section 2.1(b)(vi)(B) in respect of the Machine Space) shall be reduced by [\*\*\*\*\*] .

#### **4.3                    Authorization to Procure .**

(a) Reliance on Forecast. Client understands and acknowledges that Halo will rely on the Forecast, Commitment and Firm Orders to procure Components necessary for Halo to fulfill its obligations to supply Product under this Agreement. In addition, Client understands that to ensure an orderly supply of such Components, it may be desirable for Halo to purchase such Components in sufficient volumes to meet the anticipated requirements for Products set forth in part or all of the Forecast or such longer period as Halo and Client may agree. Accordingly, Client authorizes Halo to purchase Components sufficient to satisfy Client's Product and Packaging requirements set forth in the [\*\*\*\*\*] of the Forecast most recently provided by Client to Halo pursuant to Section 3.1 and such longer period as Halo and Client may agree in writing from time to time. If Components ordered by Halo as permitted by this Section 4.3(a) are not included in Products manufactured for Client within [\*\*\*\*\*] after the Forecasted month in respect of which such purchases were made (or such longer period as Halo and Client may agree) or if such Components have expired during such period, Client shall reimburse Halo its documented costs for procuring and testing such items.

(b) Exclusive Components. Halo shall provide Client with a list substantially in the form set forth on Schedule E (the "**Exclusive Components Purchasing Summary** ") of all Components unique to Client or Product that Halo expects to purchase pursuant to Section 2.1(b)(iii) ("**Exclusive Components** "), in keeping with the Product volumes set forth in the then-current Forecast, Commitment and Firm Orders. Halo shall provide a preliminary Exclusive Components Purchasing Summary following execution of this Agreement, a revised version following receipt of final Specifications, and thereafter an updated version on an annual basis. The Exclusive Components Purchasing Summary shall indicate which Exclusive Components have a limited shelf life and which are subject to minimum order quantities as specified by the vendor. Client shall reimburse Halo its documented costs for procuring and testing all Exclusive Components purchased by Halo for use under this Agreement that are not used to perform Manufacturing Services prior to the expiry of the Exclusive Component's shelf life.

(c) Reimbursement. Reimbursement from Client under this Section 4.3 shall be due, where applicable, within [\*\*\*\*\*] after Halo provides written notice to Client that the relevant



Component has expired. Halo shall deliver to Client documentation reasonably sufficient to support the amount of such reimbursement; *provided*, that Halo shall not be obligated to provide specific pricing information regarding any Component that is subject to confidentiality obligations between Halo and its vendor. In respect of any unused, but unexpired, Components reimbursed by Client hereunder, to the extent such Components are incorporated into Product subsequent to such reimbursement, Halo will credit Client for the amount reimbursed to Halo under this Section 4.3.

(d) Delay. Halo shall not be liable for any delay in delivery of Product if (i) Halo is unable to obtain any Component in a timely manner and (ii) Halo placed orders for such Component in keeping with this Section 4.3. In the event that any Component becomes subject to purchase lead time beyond [\*\*\*\*\*], Halo and Client will negotiate in good faith an appropriate amendment to Section 4.3(a).

#### **4.4            Shipment**

(a) Risk of Loss and Title. Halo shall ship Product to Client or its designee FCA (Incoterms 2010) the Manufacturing Site promptly following Client's authorization to ship pursuant to Section 5.6. Risk of loss of Product shall remain with Halo until Halo loads Product onto the carrier's vehicle for shipment at the shipping point, at which time risk of loss shall transfer to Client. To the extent not already held by Client, title to Product shall transfer to Client concurrently with risk of loss.

(b) Packing and Transport. Halo shall pack and label shipping containers in accordance with Applicable Law and transport guidelines, the Specifications, and Client's written instructions (to the extent not inconsistent with any of the foregoing). At Client's request and expense, merely as a convenience for Client and without any liability accruing to Halo whatsoever (including in respect of damage in transit, delivery issues, storage/shipping condition issues or export/import issues), Halo shall reasonably cooperate with Client to facilitate, as agent for Client, (i) making shipping arrangements and/or (ii) obtaining export licences or other official authorizations necessary to export the Products, such as customs clearance. Client shall arrange for insurance and shall select the freight carrier to be used to ship Products.

(c) Delay. Halo shall not be liable for any delay in delivery of Product as a result of the matters described in clauses (1), (3) and (5) of Section 2.4(a).

### **ARTICLE 5**

#### **PRICING, COSTS, invoicing and payment**

**5.1            Initial Period Fees**. Each Price and Packaging Fee set forth on Schedule A is valid from the Effective Date until [\*\*\*\*\*]; *provided*, that Halo reserves the right to revise the Price and Packaging Fee, subject to reasonable negotiation between the parties, if commercial manufacturing has not commenced under this Agreement within [\*\*\*\*\*] of the Effective Date. Halo also reserves the right to revise the Price and Packaging Fee if this Agreement is substantially amended after the Effective Date, subject to Client's written consent, which shall not be unreasonably withheld, conditioned or delayed.

**5.2 Subsequent Year Fee Adjustments.** Effective on [\*\*\*\*\*], each of the Price and Packaging Fee shall be adjusted to reflect (i) [\*\*\*\*\*], and (ii) [\*\*\*\*\*], so as to pass on to Client the actual amount of any increase or decrease in such costs. Halo shall provide in writing to Client by November 1 of each Year the updated Price and Packaging Fee for the subsequent Year, with appropriate supporting documentation; *provided*, that Halo may redact confidential portions of any supporting documents subject to obligations of confidentiality between Halo and its vendors. Such revised fee shall be effective with respect to any Product delivered by Halo after the end of the then current Year.

**5.3 Current Year Fee Adjustments.** During any Year of this Agreement, the Price and Packaging Fee shall be adjusted in accordance with this Section 5.3 to reflect extraordinary increases or decreases in Component costs due to market conditions. A material change shall be deemed to have occurred if: (i) the cost of a given Component increases or decreases by [\*\*\*\*\*] or more of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components of a given Product increases or decreases by [\*\*\*\*\*] or more of the total Component costs for such Product upon which the most recent fee quote was based. To the extent that a Price or Packaging Fee has been previously adjusted pursuant to Section 5.2 or this Section 5.3 to reflect an increase or decrease in the cost of one or more Components, the adjustments provided for in clauses (i) and (ii) above shall operate based on the costs attributed to such Component(s) at the time the last such adjustment was made. Halo shall provide in writing to Client the revised Price and/or Packaging Fee, with documentation to support both Halo's normal forecasted cost and new materially changed cost; *provided*, that Halo may redact confidential portions of any supporting documents subject to obligations of confidentiality between Halo and its vendors. Such revised Price and/or Packaging Fee shall be effective with respect to any Product delivered by Halo on or after the first day of the month following Client's receipt of Halo's notice.

**5.4 Fee Adjustments Due to Technical Changes and Productivity Improvements.**

(a) **Technical Changes.** Amendments to a Product's master batch record, Specifications or the applicable Quality Agreement requested by either Halo or Client will be implemented only following a technical and cost review by the parties, and are subject to Client and Halo reaching agreement on appropriate revisions to the Price and/or Packaging Fee and any other impacted fees under this Agreement. If Halo and Client agree to proceed with such amendment and Client accepts a proposed fee revision, Halo shall implement the proposed change on the agreed timeframe, and the revised fee shall apply only to Products that are manufactured under the amended master batch record, Specifications or Quality Agreement, as applicable. In addition, Client shall purchase from Halo any Inventory rendered obsolete as a result of such amendment based on the procedure described in Section 8.4(c), subject to the last sentence of Section 8.4.

(b) **Productivity Improvements.** Halo and Client will reasonably cooperate in continuous improvement initiatives designed to reduce Product costs. A cost reduction measure is one that reduces the internal costs or out-of-pocket expenses of either Halo or Client. If Client provides to Halo an asset or mechanism by which to reduce Product costs (e.g., Intellectual Property or capital investment, including [\*\*\*\*\*]), then Halo shall pass through to Client all of

the resulting net cost savings (net of implementation costs). If Halo provides an asset or mechanism by which to reduce Product costs, then Halo and Client shall share equally the resulting net cost savings. Halo and Client shall negotiate in good faith an appropriate vehicle for any such net cost reduction pass-through or sharing, such as a one-time payment by Halo to Client, a reduction in Price or Packaging Fee, etc. For avoidance of doubt, any on-going method improvements adopted by Halo independently as part of its internal continuous improvement initiatives in the ordinary course shall not be subject to this Section 5.4(b). Nothing in this Section 5.4(b) shall be construed to require Halo to disclose its confidential financial information or to grant any access to its financial books and records (other than in its sole discretion, or to a Regulatory Authority in connection with Section 7.2), nor to perform at no cost to Client any work that otherwise would comprise an Additional Service subject to payment by Client hereunder.

**5.5            Multi-Country Packaging Requirements.** If and when Client decides that it wishes to have Halo provide Manufacturing Services in respect of Product for countries in addition to those countries that then comprise the Territory, Client shall inform Halo of the Packaging requirements for each additional country and Halo shall prepare a quotation for consideration by Client of the relevant Packaging Fee and any revised Component costs and changeover fees for Product destined for each additional country. The agreed additional Packaging requirements and related Packaging Fee, costs and changeover fees shall be set out in a written amendment to this Agreement as contemplated by Section 14.2.

**5.6            Invoicing.**

(a)    Submission. Invoices shall be sent by fax or email to such fax number or email address as Client may provide to Halo in writing from time to time.

(b)    Product Invoices. Halo shall invoice Client for the Price and any applicable Packaging Fee for Product on the date on which Halo notifies Client that the applicable Product is released by Halo's quality assurance department. Each Product invoice shall, to the extent applicable, identify Client's Purchase Order number, Product batch numbers, names and quantities, Price, Packaging Fee, freight charges and the total amount to be remitted by Client. Halo shall also submit to Client with each shipment of Product an invoice covering such shipment.

(c)    Other Invoices. Halo shall invoice Client for all other fees due under this Agreement (including in connection with True Up Amounts, Additional Services, Components, and Consumables) as and when appropriate, including any credits under such invoices. Any fees assessed on an annual basis will be invoiced as of the first day of each Year. Each such invoice shall reference this Agreement and identify in reasonable detail the nature of the charges therein.

**5.7            Payment Terms.** Client shall pay all invoiced amounts that are not subject to a good faith dispute by Client in full within [\*\*\*\*\*] following the applicable invoice date. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. For amounts that are subject to a good faith dispute or in respect of invoices for Product that has been rejected by Client in accordance with the procedures set forth in Section 6.1, Client shall pay, within [\*\*\*\*\*] after resolution of such dispute, any amounts agreed to be due from Client pursuant

to such resolution, together with interest as provided in Section 5.8 from the original due date of such amounts to the date of the actual payment.

**5.8 Interest.** If any payment is not received by Halo by its due date, Halo may, in addition to any other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at [\*\*\*\*\*] (or, if less, the maximum amount permitted by Applicable Laws) until paid in full.

**5.9 Taxes.** All taxes, duties and other amounts assessed by any Authority (excluding tax based on net income and franchise taxes) on API, PEO, Manufacturing Services or Product are the responsibility of Client, and Client shall reimburse Halo for all such taxes, duties and amounts paid by Halo to any Authority (or such sums will be added to invoices directed at Client, where applicable).

## **ARTICLE 6**

### **PRODUCT CLAIMS AND RECALLS**

#### **6.1 Product Claims.**

(a) **Product Claims.** Client has the right to reject any portion of any shipment of Product that is alleged not to be Conforming Product (“ **Non-Conforming Product** ”) without invalidating any remainder of such shipment. Client shall inspect Product supplied by Halo upon receipt thereof and shall give Halo written notice (a “ **Deficiency Notice** ”) of all claims that Product is Non-Conforming Product within [\*\*\*\*\*] after Client’s receipt thereof (or, in the case of Latent Defects, within [\*\*\*\*\*] after discovery thereof by Client, but in no event after the expiration date of the Product), together with a sample of the Non-Conforming Product. Should Client fail to provide Halo with the Deficiency Notice within the applicable [\*\*\*\*\*] period, then the Product shall be deemed to have been accepted by Client as of the [\*\*\*\*\*] after delivery or discovery, as applicable, and Halo shall have no liability therefor.

(b) **Evaluation.** Upon receipt of a Deficiency Notice, Halo shall have [\*\*\*\*\*] to advise Client in writing that it disagrees with the Deficiency Notice. If Client and Halo fail to agree within [\*\*\*\*\*] after Halo's disagreement notice as to whether any Products identified in the Deficiency Notice are Non-Conforming Product, then Halo and Client shall mutually select an independent laboratory or qualified person, as appropriate, to evaluate whether such Products are Non-Conforming Product and the cause of any non-conformity. Such evaluation shall be binding on the parties. If such evaluation confirms that such Products are Non-Conforming Products or if Halo does not disagree with the Deficiency Notice, such Products shall be deemed properly rejected under this Section 6.1, and Halo shall bear the expenses associated with the evaluation, if any. If such evaluation determines that Product is Conforming Product, Client shall be deemed to have accepted delivery of such Products on the [\*\*\*\*\*] after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [\*\*\*\*\*] after discovery thereof by Client, but in no event after the expiration date of the Product), and Client shall bear the expenses associated with such evaluation.

(c) Shortage. Claims for shortages in the quantity of Products shipped by Halo shall be dealt with as may reasonably be agreed to by Halo and Client in the ordinary course of business.

## **6.2 Product Recalls**

(a) Records and Notice. Halo and Client shall each maintain such records as may be necessary to permit a Recall of any Product delivered to Client or customers of Client. Each of Halo and Client shall promptly notify the other by telephone (to be confirmed in writing) of any notification, event or other information, whether received directly or indirectly, that might affect the marketability, safety or effectiveness of any Product and/or that might result in a Recall of any API, PEO or Product. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by Client.

(b) Recalls. In the event (i) any Authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) Client determines that any Product should be Recalled, Halo will co-operate as reasonably requested by Client, having regard to all Applicable Laws.

## **6.3 Halo's Responsibility for Non-Conforming and Recalled Product**

(a) Non-Conforming Product. In the event Client rejects Products in accordance with Section 6.1 and defect in Non-Conforming Product is determined to have arisen primarily from Halo's failure to provide the Manufacturing Services in accordance with the Specifications, Applicable Laws (including cGMPs) and the Quality Agreement (" **Non-Compliant Services** "), Halo will, at Client's election either (i) credit Client's account for (A) the invoiced Price for such Non-Conforming Products, *plus* (B) the invoiced Packaging Fee, if any, for such Non-Conforming Products, *plus* (C) the API incorporated in such Non-Conforming Product at the API Cost (subject to the Maximum API Credit Value), *plus* (D) the PEO incorporated in such Non-Conforming Product at the PEO Cost (subject to the Maximum PEO Credit Value), *plus*, the reasonable transportation costs incurred by Client in respect of all of the foregoing, or (ii) replace such Non-Conforming Products with Conforming Products, contingent upon the receipt from Client of API and PEO necessary for the manufacture of such replacement Products, for which Halo shall pay Client at the API Cost (subject to the Maximum API Credit Value) and the PEO Cost (subject to the Maximum PEO Credit Value), respectively.

(b) Recalled Product Not Attributed to Halo Actions. Halo shall not be responsible for any aspect of any Recall (including costs), and shall be entitled to full payment for all Product delivered, if a Recall is due to reasons that cannot be primarily attributed to Halo's Non-Compliant Services. Client shall reimburse Halo for all reasonable and documented out of pocket costs and expenses incurred by Halo in assisting Client, as may be reasonably requested by Client, in investigating any such Recall.

(c) Recalled Product Attributed to Halo Actions. In the event of any Recall arising out of or resulting from Halo's Non-Compliant Services, Halo shall reimburse Client for all reasonable

and documented out-of-pocket costs and expenses incurred by Client in conducting such Recall and, at Client's election, either:

(i) credit Client's account for (A) the invoiced Price for such Recalled Product, *plus* (B) the invoiced Packaging Fee, if any, for such Recalled Product, *plus* (C) the API incorporated in such Recalled Product at the API Cost (subject to the Maximum API Credit Value), *plus* (D) the PEO incorporated in such Recalled Product at the PEO Cost (subject to the Maximum PEO Credit Value); *plus*, the reasonable transportation costs incurred by Client and not otherwise recovered by Client in respect of such Recalled Product; or

(ii) replace such Recalled Products with Conforming Products, contingent upon the receipt from Client of API and PEO necessary for the manufacture of such replacement Products, for which Halo shall pay Client at the API Cost (subject to the Maximum API Credit Value) and the PEO Cost (subject to the Maximum PEO Credit Value), respectively.

(d) Limitations. For avoidance of doubt, Halo shall have no obligation for or in connection with Non-Conforming Product or Recalled Product if any deficiencies in, or other liabilities associated with (and the parties expressly acknowledge and agree that it shall not be deemed to be Non-Compliant Services if), such Non-Conforming Product or Recalled Product [\*\*\*\*\*].

**6.4** Disposition of Non-Conforming Products. Client shall not, without Halo's prior written consent, dispose of any Non-Conforming Products in relation to which it intends to assert a claim against Halo. Halo shall bear the cost of disposition with respect to Non-Conforming Products in relation to which it bears responsibility under Section 6.3. In all other circumstances, Client shall bear the cost of such disposition.

**6.5** Customer Questions and Complaints. Client shall have the sole responsibility for responding to questions and complaints from Client's customers and for handling customer returns of Product. Questions or complaints received by Halo from Client's customers shall be promptly referred to Client in writing or by any reasonable means, including but not limited to Client's Adverse Event Hotline at [\*\*\*\*\*] or as referenced in the Quality Agreement. Halo shall cooperate and provide such information as reasonably required to allow Client to determine the cause of, respond to, and resolve any customer questions and complaints. Unless it is determined that the cause of any customer complaint is Non-Compliant Services, all costs incurred by Halo under this Section 6.5 shall be borne by Client.

**6.6** Sole Remedy. Except for Halo's indemnity obligations under Section 10.3(a) and subject to the limitations set forth in this Agreement (including Sections 10.1 and 10.2), the remedies described in this Article 6 shall be Client's sole remedy for any Non-Conforming Product and/or Non-Compliant Services. In addition, to the extent Client elects the remedy set forth in Section 6.3(c) in connection with Recalled Product, Client may not also elect the remedy set forth in Section 6.3(a) for Non-Conforming Product.



## **ARTICLE 7**

### **COOPERATION**

**7.1            Quarterly Review**. Promptly following execution of this Agreement, Halo and Client shall appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

**7.2            Communication with Authorities**. Subject to Section 7.7, Halo may communicate with any Authority, including any Regulatory Authority, regarding Product if, in the opinion of Halo's counsel, such communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law; *provided*, that unless, in the reasonable opinion of Halo's counsel, there is a legal prohibition against doing so, Halo shall permit Client to accompany and take part in any communications with the Regulatory Authority regarding Product, and to receive copies of all such communications from the Regulatory Authority regarding Product. Unless not permitted by Applicable Law, Halo shall provide notice to Client within [\*\*\*\*\*] of any communications received from any Regulatory Authority that relate to, or have the potential to affect, the Manufacturing Services. Nothing in this Agreement shall be construed to limit Client's ability to communicate with any Authority, including any Regulatory Authority, concerning the Products; *provided*, that to the extent such communication pertains to the Manufacturing Services, unless, in the reasonable opinion of Client's counsel, there is a legal prohibition against doing so, Client can request and shall permit Halo to accompany and take part in communications with the Regulatory Authority regarding Manufacturing Services, and Client will provide Halo with copies of all communications from the Regulatory Authority regarding Manufacturing Services.

**7.3            Records and Accounting by Halo**. Halo shall keep materially complete and accurate records of the manufacture, testing, storage, and shipping of Product, including master batch records, completed batch records, quality control documentation and results for all acceptance tests performed (collectively, "**Records**") and retain samples of Product as necessary to comply with Applicable Law, as well as to assist with resolving Product complaints and other similar investigations. Copies of Records and samples shall be retained for a period of [\*\*\*\*\*], or longer if required by Applicable Law, at which time Client will be consulted prior to any decisions concerning the delivery and destruction of such Records, subject to Section 14.3.

**7.4            Inspection**. Halo shall permit Client or Client's designee to inspect once annually, and any other time at which Client has reasonable cause, that portion of the Manufacturing Site where Product is manufactured and review such Records as are reasonably necessary for the purpose of assessing Halo's compliance with the Specifications and Applicable Laws, including cGMPs. Such inspection and Records review shall be conducted upon reasonable prior notice by Client (which, in the case of annual inspections, shall be not less than [\*\*\*\*\*] prior to the proposed inspection; and in the case of any inspection for which Client has reasonable cause, shall be on reasonably in advance of the proposed inspection), at a time during normal business hours and on a date mutually agreeable to Halo and Client, and shall be coordinated by the relationship managers appointed under Section 7.1. A Halo representative shall be present at all times during any such

inspection, and Client's representatives conducting such audit shall comply with Halo's standard procedures while on-site.

**7.5            Notification of Regulatory Inspections or Action.** Halo shall notify Client within [\*\*\*\*] of learning of any inspections by any Regulatory Authority, and if such inspection specifically involves any Product, Client shall have the right to attend any such inspection. Halo shall furnish to Client (a) within [\*\*\*\*] after receipt, any report or correspondence issued by the FDA or other Regulatory Authority in connection with such inspection, including, but not limited to, any FDA Form 483 (list of Inspectional Observations) or applicable portions of any FDA Warning Letters that pertain to the Product in the Territory, and (b) not later than [\*\*\*\*] prior to the time it provides to the FDA or other Regulatory Authority, copies of proposed responses or explanations relating to items set forth above (each, a “ **Proposed Response** ”), in each case redacted of trade secrets or other confidential or proprietary information of Halo that are unrelated to its obligations under this Agreement or to Product. Halo shall discuss with Client and consider in good faith any comments provided by Client on the Proposed Response. After the filing of a response with the FDA or other Regulatory Authority, Halo shall notify Client and provide Client with copies of any further contacts with such Regulatory Authority relating to the subject matter of the response.

**7.6            Reports.** On an annual basis, Halo will provide Client with a copy of all Product data in its control (including release test results, complaint test results, and all investigations in manufacturing, testing and storage) that Client reasonably requires in order to complete any filing required by any Regulatory Authority, including an annual report within the meaning of 21 C.F.R. § 314.81(b)(2). At Client's request, Halo will provide Client with a copy of the annual product review report within the meaning of 21 C.F.R. § 211.180(e). Any additional reports requested by Client beyond the scope of cGMPs and customary requirements of Regulatory Authorities shall be subject to an additional fee to be agreed upon between Halo and Client.

**7.7            Regulatory Filings.**

(a)    Regulatory Authority. Client shall have the sole responsibility for filing all Product-specific documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Halo shall assist Client, to the extent consistent with Halo's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible. In addition to its obligations pursuant to Section 2.5, Halo shall have the sole responsibility for filing all documents with Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority licensure of the Manufacturing Sites, including such licenses as may be required to perform services generally of the nature of the   Manufacturing Services.

(b)    Verification of Data. At least [\*\*\*\*] prior to filing in connection with obtaining regulatory approval of the Products any documents with any Regulatory Authority that incorporate data generated by Halo, Client shall provide Halo with a copy of the documents incorporating such data so as to give Halo the opportunity to verify the accuracy of such documents as they relate to



the Halo generated data. Upon completion of the review, Halo shall return or destroy any and all documents related to its review as instructed by Client.

(c) Verification of CMC. At least [\*\*\*\*\*] prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC ") related to any marketing authorization, such as a New Drug Application or Abbreviated New Drug Application, Client shall provide Halo with a copy of the CMC documents which have relied upon Halo data for preparation. Such disclosure shall permit Halo to verify that the CMC accurately describes the work that Halo has performed and the manufacturing processes that Halo will perform pursuant to this Agreement. Client shall provide Halo with copies of those sections of FDA filings at the time of submission that contain chemistry, manufacturing and controls information derived from Halo data regarding the Product. Such copies and FDA filings shall constitute Client's Confidential Information.

(d) Deficiencies. If, acting reasonably, Halo determines that any of the information provided by Client in accordance with clause (b) or (c) above is inaccurate or deficient, Halo shall notify Client in writing of such matter within [\*\*\*\*\*] of receipt of documents from Client. The parties shall work together to have such matters resolved prior to Client's submission to the Regulatory Authority; *provided*, that Client shall have the final decision as to inclusion of any information in such submissions so long as such information does not obligate Halo to pay any money or perform any task or obligation beyond the Manufacturing Services provided for hereunder.

**7.8 Quality Agreement**. If Halo and Client have executed a Quality Agreement prior to the Effective Date, it shall be attached hereto as Schedule H (and if such Quality Agreement is by only one or two of the entities included in the term "Client", then, by signing this Agreement, each Client entity who is not party to such Quality Agreement hereby agrees that such Quality Agreement applies equally to it for purposes of this Agreement). If Halo and Client have not executed a Quality Agreement prior to the Effective Date, a form of Quality Agreement shall be attached hereto as Schedule H and, as soon as reasonably practicable after the signing of this Agreement (and in any event prior to Halo's performance of any Manufacturing Services), Halo and Client shall negotiate in good faith and enter into a Quality Agreement in such form and that reflects the terms and conditions of this Agreement. Following signature of such Quality Agreement, the parties shall replace the form at Schedule H with such executed Quality Agreement. The Quality Agreement shall in no way determine financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMPs, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern. |

**ARTICLE 8**  
**TERM AND TERMINATION**

**8.1           Term.** This Agreement shall become effective as of the Effective Date and shall continue for five (5) Years from the date of Client's first Firm Order (" **Initial Term** "), unless terminated earlier by Halo or Client in accordance with Section 8.2. The Initial Term shall automatically renew for successive terms of two (2) Years each (each, a " **Renewal Term** ", and together with the Initial Term, the " **Term** ") unless either Halo or Client gives written notice to the other of its intention to terminate this Agreement at least six (6) months prior to the end of the then-current Initial Term or Renewal Term, as applicable.

**8.2           Early Termination.**

(a)       Breach. Either Halo or Client may terminate this Agreement upon written notice to the other party effective immediately if such other has failed to remedy a material breach of this Agreement within thirty (30) calendar days following receipt of a written notice that describes the material breach in reasonable detail and expressly states that it is a notice under this Section 8.2(a), *provided* , however, if the material breach cannot be cured within thirty (30) calendar days, then if the material breach is capable of being cured and the defaulting party substantially commences in good faith the cure within twenty (20) calendar days after receipt of the written notice of material breach and completes the cure within sixty (60) days from receipt of such written notice, then the non-defaulting party shall not be permitted to terminate this Agreement as a result of such material breach . If the defaulting Party is solely Halo, then the Requirements Obligation under Section 2.1 shall be waived for the foregoing thirty (30) and sixty (60) day periods, the Quarterly Minimum shall be reduced on a *pro rata* basis for the foregoing thirty (30) and sixty (60) day periods, and Halo will reimburse Client for any reasonable, out-of-pocket costs actually incurred by Client to itself fulfill or have fulfilled Manufacturing Services under Article 2 during such periods in which the Requirements Obligation is waived .

(b)       Bankruptcy. Either Halo or Client may terminate this Agreement immediately without further action (including without any written notice to the other) in the event that (i) any one of the entities included in the term "Client" or Halo, respectively, is declared insolvent or bankrupt by a court of competent jurisdiction, and such declaration or order remains in effect for a period of sixty (60) days, (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by any one of the entities included in the term "Client" or Halo, respectively, or (iii) this Agreement is assigned by any one of the entities included in the term "Client" or Halo, respectively, for the benefit of creditors.

(c)       Regulatory Considerations. Client may terminate this Agreement as to any Product and applicable portion of the Territory upon thirty (30) days' prior written notice to Halo in the event that (i) any Regulatory Authority takes any action or raises any objection that prevents Client from importing, exporting, purchasing or selling such Product in all or part of the Territory, or (ii) subject to Section 8.3, Client elects to discontinue selling or otherwise withdraws from the market such Product in all or part of the Territory.

(d) Force Majeure. Either Halo or Client may terminate this Agreement upon written notice as permitted by Section 14.1 (Force Majeure).

**8.3** Product Discontinuation. Client shall use commercially reasonable efforts to provide at least [\*\*\*\*] advance notice to Halo if it intends to no longer order Manufacturing Services for a Product due to its election to discontinue or otherwise withdraw from the market any Product in all or part of the Territory.

**8.4** Obligations on Termination. If this Agreement expires or is terminated in whole or in part for any reason, then, in addition to the applicable terms of Section 8.5:

(a) Work in Process. At Client's election, Halo shall either (i) complete any Product that is a work in process, which Product shall be subject to Section 8.4(b), or (ii) or cease such work and transfer such work in process into storage containers, which work in process shall be subject to Section 8.4(c); it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) or 8.2(b), clause (ii) above shall automatically apply;

(b) Product. Client shall take delivery of and pay for, at the Price and Packaging Fee in effect at the time, all completed, undelivered Conforming Product that Halo has produced pursuant to a Firm Order;

(c) Inventory. Except in the event of termination of this Agreement for Halo's uncured material breach, Client shall purchase, at Halo's cost, all Inventory then in stock or that is later delivered by a Third Party vendor pursuant to non-cancellable orders, and shall reimburse Halo for any cancellation fees assessed by Third Party vendors for Inventory orders that are cancellable; *provided*, that Halo provides to Client, upon reasonable request, copies of vendor purchase orders and/or contracts to support Halo's assertion that an order is non-cancellable; *provided further*, that Halo may redact confidential portions of any such supporting documents pursuant to obligations of confidentiality between Halo and the applicable vendor.

(d) Client-Supplied Materials. Halo shall return to Client all unused API and PEO, and deliver to Client all Inventory paid for by Client pursuant to clause (c) above;

(e) Records and Samples. Halo shall maintain reserve samples and batch production records in accordance with Applicable Law;

(f) Stability. At Client's election, Halo shall either (i) continue to perform any ongoing stability testing or (ii) ship the stability samples to Client; it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) or 8.2(b), clause (ii) above shall automatically apply;

(g) Technology Transfer. At Client's request and so long as Client is not in breach of Article 11, Halo shall permit Third Parties to access to the Manufacturing Sites for purposes of effecting a technology transfer of Client's Product and Specifications, subject to Halo's prior written consent, which shall not be unreasonably withheld ( *provided*, that if Client is in breach of Article 11, but not in material breach of Article 11, then the foregoing right of qualified access

shall be limited to Third Parties that are not direct competitors of Halo (i.e., a North America-based contract manufacturing organizations)); and

(h) Quarterly Minimum. If termination occurs prior to the end of the Initial Term and such termination is by Halo under Section 8.2(a), 8.2(b), or 8.2(d) or by Client under Section 8.2(c) (except where the basis for such termination is the result of an action or objection by a Regulatory Authority that is not due to the fault of Client (e.g., if a Regulatory prohibits the sale of opioid products)), Client shall pay Halo an amount equal to (i) if termination is not concurrent with the end of a Contract Quarter, the amount that would have been due from Client to Halo under Section 4.2 if the Agreement had remained in effect through the end of the then-current Contract Quarter and Client had ordered no more Product during the then-current Contract Quarter *plus* (ii) the amount that would have been due from Client to Halo under Section 4.2 for each remaining full Contract Quarter of the Initial Term, but not to exceed [\*\*\*\*\*], if the Agreement had remained in effect through the end of the Initial Term and Client had not ordered any Product during any such Contract Quarter. Notwithstanding anything to the contrary herein, payment by Client of the amounts set forth in this Section 8.4(h) shall constitute Halo's sole and exclusive remedy for termination of this Agreement by Halo under Section 8.2(a), 8.2(b), or 8.2(d) or by Client under Section 8.2(c) (subject to the other provisions of this Section 8.4);

with any costs incurred by Halo to comply with the obligations in the foregoing clauses (a) – (h), including shipping and related expenses, to be borne by Client, except in the event of termination of this Agreement by Client pursuant to Section 8.2(a) or 8.2(d), in which case Halo shall bear all such expenses. In lieu of taking possession of any of the materials described in clause (b), (c) or (d) above, Client may direct Halo to destroy such items, which Halo shall cause to be done at Client's cost except as provided in the preceding sentence.

**8.5** Survival. Any termination or expiration of this Agreement shall not affect any obligations or payments due hereunder and outstanding as of the date of such termination or expiration, nor shall it prejudice any other rights or remedies that a party may have under this Agreement. Notwithstanding any termination or expiration of this Agreement for any reason, the parties' rights and obligations under the following provisions shall survive and continue in effect in accordance with their respective terms: Sections 2.1(b)(vi)(D), 3.6, 5.6 – 5.9, 7.3, 8.4, 8.5 and 9.4, and Articles 6, 10, 11, 12 (excluding Section 12.1(b)), 13 and 14.

## **ARTICLE 9**

### **REPRESENTATIONS, WARRANTIES AND COVENANTS**

**9.1** Authority. Each party represents and warrants to the other that (a) it has the full right and authority to enter into this Agreement, (b) it is in good standing in its jurisdiction of organization and all jurisdictions in which it operates, (c) the execution and delivery of this Agreement and the performance of such its obligations hereunder do not conflict with, or constitute a default or require any consent under, any contractual obligation of such party, and (d) it will comply with all Applicable Laws in performing its obligations under this Agreement.

**9.2                    Client Warranties.** Client covenants, represents and warrants to Halo that:

(a)        to the best of Client's knowledge, the preliminary copy of the Specifications provided by Client to Halo further to Section 3.3 is true and accurate in all material respects, and, to the best of Client's knowledge, there will be no material change to such Specifications;

(b)        it shall at all times comply with all material Applicable Laws relating to its activities under this Agreement, and in particular (i) all Product delivered to Client by Halo hereunder shall be held, used, distributed, sold and otherwise disposed of by or on behalf of Client in accordance with all Applicable Laws and (ii) all artwork, the content of all Packaging, and all other Specifications delivered by or on behalf of Client to Halo for use in the Manufacturing Services shall comply with Applicable Law;

(c)        it owns or is licensed (with the right to sublicense to Halo) to all right, title and interest in and to all Intellectual Property rights relating to the Product (other than Halo's Intellectual Property) provided by Client to Halo for use in connection with providing Manufacturing Services, and such Intellectual Property (i) may lawfully be used by Halo in connection with providing Manufacturing Services and (ii) so long as Halo uses such Intellectual Property solely as contemplated by this Agreement, such use, to the best of Client's knowledge, does not and will not infringe, violate or misuse any Third Party Rights;

(d)        to the best of Client's knowledge, the manufacture of the Product in accordance with the Specifications, and the use of the API and PEO in the Product in the Territory, do not and will not infringe, violate or misuse any applicable United States or foreign Third Party Rights, and it has no knowledge of any actual or threatened claims, actions or proceedings alleging the infringement, violation or misuse of any Third Party Rights in connection with the manufacture of the Product or the use of the API or PEO in the Product in the Territory; and

(e)        Client shall have contractually required its suppliers of API and PEO provided to Halo hereunder to have been manufactured in accordance with Applicable Law, including cGMPs, and at the time of delivery under Section 3.4 to meet all applicable Specifications and not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws;

(f)        the Injection Molding Machines are of a size, design capacity, and manufacture selected by Client, and as of the Effective Date the IM Machines are (i) suitable for Client's purposes, (ii) sufficient to produce the quantities of Product that Client expects to order hereunder subject to the capacity constraints described in Section 3.2(c), (iii) are compliant with cGMPs, and (iv) have been delivered and installed in good operating condition; and

(g)        each of the API Cost and PEO Cost accurately reflects Client's actual, out-of-pocket cost to procure the API and PEO, respectively, from its Third Party vendors and provide it to Halo.

**9.3                    Halo Warranties.** Halo covenants, represents and warrants to Client that:

(a)        to the best of Halo's knowledge, there are no Third Party Rights related to Halo's Intellectual Property that would be infringed, violated or misused by Halo's performance of the Agreement ;

(b)        it has no knowledge of any claims, actions or other actual or threatened legal proceedings or investigations by any Regulatory Authority, the subject of which is (i) the infringement, violation or misuse of Third Party Rights related to any Halo's Intellectual Property or (ii) the violation of Applicable Law by Halo or the Manufacturing Sites;

(c)        it does not and will not use in the performance of its obligations under this Agreement the services of any individual debarred or suspended under 21 U.S.C. §335(a) or (b);

(d)        it does not have and will not hire as an officer or employee any individual who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the *Federal Food, Drug, and Cosmetic Act* ; and

(e)        all Product provided to Client hereunder have been manufactured in accordance with the Quality Agreement, the manufacturing process set forth in the Product Specifications (subject to permitted deviations) and Applicable Law, including cGMPs, and shall at the time of delivery under Section 4.4(a) meet all Specifications and not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided* , that no representation or warranty is made by Halo to the extent of (and Halo shall not be liable for any defect in Product attributable to) any of the matters described in Section 6.3(d) or clauses (2) and (4) of Section 2.4(a) (the foregoing, the “ **Product Warranty** ”).

**9.4                    Limited Warranty.** NO PARTY MAKES ANY REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS ARTICLE 9. HALO EXPRESSLY DISCLAIMS THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS.

**ARTICLE 10**  
**REMEDIES, INDEMNITIES and INSURANCE**

**10.1                    No Consequential Damages.** Except for [\*\*\*\*\*] , under no circumstances whatsoever shall either Halo or Client be liable to the other (or any related Person) in contract, tort, negligence, breach of statutory duty or otherwise for (a) any (direct or indirect) loss of profits (including lost sales, business interruption or lost business opportunities), revenues, production, anticipated savings, data, business or goodwill or (b) any other liability, damage, cost or expense of any kind incurred by any other party of an incidental, indirect, consequential, exemplary, punitive or special nature, regardless of any notice of the possibility of such damages.



## **10.2            Limitation of Liability**

(a)     API. Except as expressly set forth in Sections 2.1(b)(i), 2.3(e), 6.3(a) and 6.3(c) of this Agreement, under no circumstances whatsoever shall Halo be responsible for any loss, damage or destruction of API. Halo's maximum aggregate liability for loss or damage to all API under this Agreement, including Sections 2.1(b)(i), 2.3(e), 6.3(a) and 6.3(c), shall not exceed the Maximum API Credit Value in any given Year.

(b)     PEO. Except as expressly set forth in Sections 2.1(b)(ii), 2.3(e), 6.3(a) and 6.3(c) of this Agreement, under no circumstances whatsoever shall Halo be responsible for any loss, damage or destruction of PEO. Halo's maximum aggregate liability for loss or damage to all PEO under this Agreement, including Sections 2.1(b)(ii), 2.3(e), 6.3(a) and 6.3(c), shall not exceed the Maximum PEO Credit Value in any given Year.

(c)     Maximum Liability. Halo's maximum liability under this Agreement resulting from a breach of its representations, warranties or other obligations under this Agreement shall not exceed [\*\*\*\*\*]. The foregoing shall not apply to [\*\*\*\*\*].

(d)     For the avoidance of doubt, any amounts paid or credited to Client by Halo under this Agreement (i) in respect of lost, damaged or destroyed API shall not exceed the Maximum API Credit Value, (ii) in respect of lost, damaged or destroyed PEO shall not exceed the Maximum PEO Credit Value, and (iii) in respect of any and all liabilities under this Agreement (including in connection with API and PEO) shall not exceed the cap set forth in clause (c) above.

## **10.3            Indemnification**

(a)     By Halo. Halo shall indemnify and hold harmless Client, its Affiliates, and their respective officers, employees and agents (“ **Client Indemnitees** ”) from and against any and all losses, claims, damages, liabilities, obligations, penalties, judgments, awards, costs, expenses, and disbursements, including reasonable attorneys' fees and expenses (collectively, “ **Losses** ”), in connection with any claim, suit or action asserted by a Third Party (“ **Third Party Claim** ”) caused by, relating to, based upon, arising out of or in connection with: (a) any breach by Halo of any of Halo's representations, warranties or covenants under this Agreement; (b) any actual or alleged infringement or violation of any Third Party's patent, trade secret, copyright, trademark or other proprietary rights by Halo's Intellectual Property (excluding Inventions allocated to Halo pursuant to Section 12.2(b)); or (c) Halo's willful misconduct or negligence; except in each case to the extent any such Losses were caused by or arose out of any Client Indemnitee's (i) breach of the representations, warranties or covenants set forth herein, (ii) willful misconduct or negligence or (iii) other matter subject to indemnity by Client pursuant to Section 10.3(b).

(b)     By Client. Client shall indemnify and hold harmless Halo, its Affiliates, and their respective officers, employees and agents (“ **Halo Indemnitees** ”) from and against any and all Losses in connection with any Third Party Claim caused by, relating to, based upon, arising out of or in connection with: (a) breach of any of Client's representations, warranties, or covenants under this Agreement; (b) any actual or alleged infringement or violation of any Third Party's patent, trade secret, copyright, trademark or other proprietary rights by Intellectual Property or materials

provided by Client, including API, (c) product liability arising from defective API or PEO; (d) Client's willful misconduct or negligence; or (e) the promotion, distribution, use, misuse, sale or effect of the API or Product; except in each case to the extent any such Losses were caused by or arose out of any Halo Indemnitee's (i) breach of the representations, warranties or covenants set forth herein, (ii) willful misconduct or negligence or (iii) other matter subject to indemnity by Halo pursuant to Section 10.3(a).

(c) Procedure.

(i) Claims. As promptly as is reasonably practicable after becoming aware of a claim for indemnification under this Agreement, but in any event no later than [\*\*\*\*] after becoming aware thereof, the party claiming indemnification (the "**Indemnified Person**") shall give written notice to the party from which indemnification is sought (the "**Indemnifying Person**") of such claim in accordance herewith (the "**Claim Notice**"); *provided*, that the failure of the Indemnified Person to give such notice shall not relieve the Indemnifying Person of its obligations under this Section 10.3 except to the extent (if any) that the Indemnifying Person shall have been prejudiced thereby. The Claim Notice shall set forth in reasonable detail (A) the facts and circumstances giving rise to such claim for indemnification, including all relevant, reasonably available, material supporting documentation, (B) the nature of the Losses suffered or incurred or expected to be suffered or incurred, (C) a reference to the provisions of this Agreement in respect of which such Losses have been suffered or incurred or are expected to be suffered or incurred, and (D) the amount of Losses actually suffered or incurred and, to the extent the Losses have not yet been suffered or incurred, a good faith estimate of the amount of Losses that could be expected to be suffered or incurred.

(ii) Participation. The Indemnifying Person may, at its own expense, (i) participate in the defense of any such Third Party Claim and (ii) upon notice to the Indemnified Person, at any time during the course of any such Third Party Claim, assume the defense thereof with counsel of its own choice. In the event of such assumption, the Indemnifying Person shall have the exclusive right, subject to clause (A) in the proviso in Section 10.3(c)(iii), to settle or compromise such Third Party Claim. If the Indemnifying Person assumes such defense, the Indemnified Person shall have the right (but not the duty) to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Person (subject to the foregoing provisions of this Section 10.3(c)(ii)). Whether or not the Indemnifying Person chooses to defend any such Third Party Claim, all parties hereto shall cooperate in the defense thereof.

(iii) Settlement or Compromise. Any settlement or compromise made or caused to be made by the Indemnified Person (unless the Indemnifying Person has the exclusive right to settle or compromise under Section 10.3(c)(ii)) or the Indemnifying Person, as the case may be, of any such Third Party Claim shall also be binding upon the Indemnifying Person or the Indemnified Person, as the case may be, in the same manner as if a final judgment or decree had been entered by a court of competent jurisdiction in the amount of such settlement or compromise; *provided*, that (i) no obligation, restriction or Loss shall be imposed on the Indemnified Person as a result of such settlement or compromise without its prior written consent and (ii) the Indemnified Person



will not compromise or settle any Third Party Claim without the prior written consent of the Indemnifying Person, in each case, which consent shall not be unreasonably withheld.

(iv) Mitigation.

(A) Each Indemnified Person shall use commercially reasonable efforts to mitigate any Losses that such Indemnified Person asserts or is reasonably likely to assert under this Section 10.3; *provided*, however, that the use of such commercially reasonable efforts shall not be a condition to bringing a claim for indemnification hereunder in respect of such Losses; and *provided*, further, that if an Indemnified Person shall fail to make such commercially reasonable efforts to mitigate any such Losses, then, notwithstanding anything to the contrary contained in this Agreement, no Indemnifying Person shall be required to indemnify any Indemnified Person for that portion of any Losses that could reasonably be expected to have been avoided if the Indemnified Person had made such efforts.

(B) Notwithstanding anything to the contrary contained in this Agreement, the amount of any Losses incurred or suffered by any Indemnified Person shall be calculated after giving effect to (1) any insurance proceeds received by the Indemnified Person (or any of its Affiliates) with respect to such Losses and (2) any recoveries obtained by the Indemnified Person (or any of its Affiliates) from any other Third Party in respect of such Losses, and each Indemnified Person shall exercise commercially reasonable efforts to obtain such proceeds, benefits and recoveries; *provided*, however, that such exercise shall not be a condition to bringing a claim for indemnification hereunder in respect of such Losses. If any such proceeds, benefits or recoveries are received by an Indemnified Person (or any of its Affiliates) with respect to any Losses after an Indemnifying Person has made a payment to the Indemnified Person with respect thereto, the Indemnified Person (or such Affiliate) shall promptly pay to the Indemnifying Person the amount of such proceeds, benefits or recoveries (up to the amount of the Indemnifying Person's payment).

(C) Upon making any payment to an Indemnified Person in respect of any Losses, the Indemnifying Person will, to the extent of such payment, be subrogated to all rights of the Indemnified Person (and its Affiliates) against any Third Party in respect of the Losses to which such payment relates. Such Indemnified Person (and its Affiliates) and Indemnifying Person will execute upon request all instruments reasonably necessary to evidence or further perfect such subrogation rights.

**10.4 Insurance.**

(a) Coverage. Each party shall purchase and maintain insurance, at its own expense, as required to protect Client and Halo as follows:

(i) Client:

(A) Commercial General Liability Insurance (Primary) with limits of not less than [\*\*\*\*\*] per occurrence and in the aggregate for bodily injury, personal injury and property damage, with coverage for blanket contractual liability, independent contractors and

severability of interest; which insurance may be satisfied through a combination of primary and umbrella liability insurance;

(B) Automobile Liability with a limit of liability not less than [\*\*\*\*\*] per occurrence combined single limit for bodily injury (including death) and property damage liability, with coverage for owned, non-owned and hired vehicles; and

(C) Products and Completed Operations Insurance with limits of not less than [\*\*\*\*\*] per occurrence and in the aggregate for bodily injury or property damage.

(ii) Halo: \_

(A) Commercial General Liability Insurance (Primary) with limits of not less than [\*\*\*\*\*] per occurrence and in the aggregate for bodily injury, personal injury and property damage, with coverage for blanket contractual liability, products and completed operations, independent contractors and severability of interest;

(B) Automobile Liability with a limit of liability not less than [\*\*\*\*\*] per occurrence combined single limit for bodily injury (including death) and property damage liability, with coverage for owned, non-owned and hired vehicles;

(C) Excess or Umbrella Coverage of not less than [\*\*\*\*\*] ; and

(D) Professional Liability (errors and omissions) insurance with limits of not less than [\*\*\*\*\*] per occurrence and in the aggregate.

(b) Additional Requirements. The foregoing insurance, excluding auto, shall be on a claims made basis, shall remain in force throughout the Term and for [\*\*\*\*\*] following expiration or termination of this Agreement, and shall be maintained with companies having an A.M. Best's rating of A- VII or better. Each party shall provide each other party with certificates of insurance evidencing the required insurance on written request. In no event shall work be performed until such evidence of the required insurance has been furnished. Each party shall give each other party at least [\*\*\*\*\*] prior written notice in the event of cancellation or non-renewal of any such required insurance. Each party shall name each other party, its agents and employees, as additional insureds on all policies of required insurance.

**10.5 Reasonable Allocation of Risk.** The provisions of this Agreement (including this Article) are reasonable and create a reasonable allocation of risk having regard to the relative profits the parties respectively expect to derive from the Products; and that Halo, in its fees for the provision of the Manufacturing Services, has not accepted a greater degree of the risks arising from the manufacture, distribution, sale and use of the Products, based on the fact that Client has developed the Products and requires Halo to manufacture and label the Products strictly in accordance with the Specifications; and that Client and not Halo is in a position to inform and advise potential users of the Products as to the circumstances and manner of use of the Products.

## **ARTICLE 11**

### **CONFIDENTIALITY**

**11.1            Confidentiality.**        The Parties agree that the Master Confidentiality Agreement, dated [\*\*\*\*\*], between the Parties (the “ **Master Confidentiality Agreement** ”) shall govern the Parties’ and their respective Affiliates’ confidentiality and non-use obligations with respect to Confidential Information (as defined therein) provided or communicated in connection with this Agreement; provided, that:

(a)        Section 3.6 is hereby amended by adding the following to its end: “In addition, (i) the receiving Party is not required to return or destroy any Confidential Information if doing so would violate any applicable law, regulation or court order, (ii) the receiving Party shall not be required to expunge any minutes or written consents of its Board of Directors (or equivalent), and (iii) to the extent that the receiving Party’s computer back-up or archiving procedures create copies of Confidential Information, the receiving Party may retain such copies for the period it normally archives backed-up computer records, so long as such copies are not readily accessible and are not used or consulted for any purpose other than disaster recovery. Any Confidential Information retained pursuant to the foregoing sentence shall remain subject to the provisions of this Section 3.2.”

(b)        Section 4.6 is hereby amended by including for Halo the contact information set forth in Section 14.4 of this Agreement.

**11.2            Publicity.** Neither Halo nor Client will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby, including identifying the other as a business partner or in connection with any scholarly or industry publications or presentations, without the other’s express prior written consent. The foregoing shall not apply to the extent disclosure is required under Applicable Laws, by any Authority or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the disclosing party shall reasonably consult with and consider the other party’s comments as to the form, nature and extent of the press release or public disclosure prior to issuing or making the disclosure.

## **ARTICLE 12**

### **INTELLECTUAL PROPERTY**

#### **12.1            Intellectual Property.**

(a)        Existing Items. Subject to the other provisions of this Article 12: (a) all Intellectual Property owned by or licensed by Third Parties to a party or any of its Affiliates shall be owned by such party; (b) neither Halo nor Client has, nor shall it acquire, any interest in any of the other’s Intellectual Property except to the extent expressly set forth in this Agreement, and (c) each of Halo and Client agrees not to use any Intellectual Property of the other except as specifically authorized by the other or as required for the performance of its obligations under this Agreement.

(b) License to Halo. For the Term, Client hereby grants to Halo a non-exclusive, paid-up, royalty-free, non-transferable, irrevocable license to use Client's Intellectual Property in connection with the Manufacturing Services

## **12.2            Inventions**

(a) Client Inventions. As between Halo and Client, all Inventions generated or derived by or on behalf of Halo or any of its employees, contractors or agents in the course of performing the Manufacturing Services, to the extent specific to, or dependent upon, the development, manufacture, use and sale of Client's Product, and all Intellectual Property pertaining to such Inventions, shall be the exclusive property of Client. Such Inventions are included in the Intellectual Property licensed to Halo under Section 12.1(b).

(b) Halo Inventions. As between Halo and Client, all Inventions generated or derived by or on behalf of Halo or any of its employees, contractors or agents in the course of performing the Manufacturing Services to the extent not specific to, or dependent upon Client's Product, and which have application to manufacturing processes or formulation development of drug products or drug delivery systems generally, and all Intellectual Property pertaining to such Inventions, shall be the exclusive property of Halo (the "**Broader Intellectual Property Rights**"). Halo hereby grants to Client a perpetual, non-terminable, irrevocable, non-exclusive, paid-up, royalty-free, sublicensable license to use Halo's Broader Intellectual Property Rights to manufacture or have manufactured, use, sell, offer for sale and import Client's Product.

(c) Disclosure. Halo shall submit to Client a written description of all Inventions generated or derived by or on behalf of Halo or any of its employees, contractors or agents in the course of performing the Manufacturing Services, including any Broader Intellectual Property Rights. Client may disclose Broader Intellectual Property Rights in any patent application claiming Client's Inventions, as Client may reasonably require to support the claimed subject matter of such patent application, subject to Halo's prior written approval, which shall not be unreasonably withheld.

(d) Each of Halo and Client shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

## **ARTICLE 13** **DISPUTE RESOLUTION**

**13.1            Escalation**. Halo and Client shall try to resolve any dispute arising out of or in connection with this Agreement other than a dispute determined in accordance with Section 6.1(b) (a "**Dispute**") amicably between themselves before resorting to any formal dispute resolution proceeding. To this end, either Halo or a single Client entity designated by the Client entities to act on behalf of all Client entities (the "**Client Party**") may send a notice of Dispute to the other, whereupon each of them shall appoint, within [\*\*\*\*\*], a single, senior representative having full power and authority to resolve the Dispute (a "**Facilitator**"). The Facilitators shall meet and discuss as necessary to try to resolve the Dispute as quickly as practicable.

**13.2      Technical Disputes** . Where a Dispute relates exclusively to technical aspects of the Manufacturing Services or related activities under this Agreement (a “ **Technical Dispute** ”), the Facilitators shall be competent to address the technical nature of the issues in question. If, despite their reasonable efforts, the Facilitators have not resolved the Technical Dispute within a reasonable period of time given the nature of the issue, but in any event within [\*\*\*\*\*] of the date of the Dispute notice, the Technical Dispute shall, at the request of either Halo or the Client Party, be referred for determination to an expert in accordance with Schedule F . If such parties cannot agree whether a dispute is a Technical Dispute, Section 13.3 shall govern. For the avoidance of doubt, nothing in this Agreement (including Schedule F ) is intended to or shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether any Product is to be released for sale or distribution.

**13.3      Commercial Disputes** . If Halo or the Client Party fails to timely appoint a Facilitator or if, despite their reasonable efforts, the Facilitators have not resolved a Dispute (other than a Technical Dispute) within [\*\*\*\*\*] from the date of the Dispute notice, the Dispute shall immediately be referred to the President of Halo and the Client Party (or such other officer as he/she may designate), who will meet and discuss as necessary to try to resolve the Dispute. Should such officers fail to resolve the Dispute, either Halo or the Client Party may resort to a court of competent jurisdiction or any other method of binding dispute resolution on which Halo and the Client Party may agree.

**13.4      Jurisdiction; Language** . Any Dispute resolution proceeding under this Article 13 shall be conducted in the jurisdiction of New Jersey, if Halo is the defendant party, or in Pennsylvania if any one or more Client entities are the defendant party(ies); in the English language.

**13.5      Prevailing Party** . As between Halo and Client, the party that prevails in any Dispute resolution proceeding shall have the right to recover from the other any reasonable attorneys’ fees and costs incurred by reason of such proceeding.

## **ARTICLE 14**

### **MISCELLANEOUS**

**14.1      Force Majeure** . No party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by: any strikes, labor disputes of whatever nature, other labor disturbances, or lockouts; quarantines or communicable disease outbreaks; acts of government or state, embargos, or compliance with any order or regulation of any Authority acting within color of right; civil commotion, insurrection, riots, wars, or acts of terrorism; fires, floods, storms, or other acts of God; interruption of or delay in transportation; lack of, prevention in, or hindrance in obtaining energy, fuel, power, other utilities; failure of suppliers or lack of or inability to obtain components; or any other reason, cause or contingency beyond the control and without fault or negligence of the party affected thereby (a “ **Force Majeure Event** ”). If Halo or Client claims a right to excused performance under this Section 14.1 , it shall immediately notify the other in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event. If Halo or Client’s performance of any obligation under this Agreement is delayed owing to a Force Majeure Event for any continuous period of more than [\*\*\*\*\*], the other may

terminate this Agreement without penalty upon written notice to Halo or Client, respectively. No party shall be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) that would otherwise be due and payable under this Agreement. In addition, Client may not claim a right to excused performance under this Section 14.1 unless all the entities included in the term "Client" are subject to the applicable Force Majeure Event.

**14.2      Additional Products and Expanded Territory**. Additional products and countries may be added to this Agreement upon the parties written agreement, and such additional products and countries shall be governed by the general conditions hereof. The parties shall amend or supplement this Agreement (including the Schedules) as necessary to reflect their agreement with respect to Product-specific or country-specific terms, including Price, Packaging Fee and Territory.

**14.3      Right to Dispose and Settle**. If Halo requests in writing Client's direction with respect to disposal of any Inventory, API, equipment, Records, samples or other items belonging to Client and is unable to obtain a response from Client within [\*\*\*\*\*] after making reasonable efforts to do so, Halo shall have the right to dispose of such items at Client's expense (which may be by set off against any credit on Client's account).

**14.4      Notices**. Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to Halo or Client, as the case may be, by personal delivery, by facsimile communication, by delivery via nationally recognized overnight courier service, by first class mail postage prepaid, or by PDF attachment to an email or similar electronic transmission to the mailing address, facsimile number or email address set forth below:

If to Client:

Egalet Corporation  
600 Lee Road, Suite 100  
Wayne, PA 19087 USA  
Attention: [\*\*\*\*\*]  
Facsimile No: [\*\*\*\*\*]  
Email (optional): [\*\*\*\*\*]

If to Halo:

Halo Pharmaceutical, Inc.  
30 North Jefferson Road  
Whippany NJ 07981 USA  
Attention: [\*\*\*\*\*]  
Facsimile No.: [\*\*\*\*\*]  
Email (optional): [\*\*\*\*\*]

or to such other contact information provided to the other party in accordance with the terms of this Section 14.4 . Notices or written communications made or given by personal delivery, overnight courier service, facsimile or email shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, [\*\*\*\*] after being deposited in the United States mail, postage prepaid or upon receipt, whichever is sooner. For the avoidance of doubt, Halo's giving of notice to Egalet Corporation in accordance with this Section 14.4 shall suffice for notice also to Egalet Ltd. and Egalet US Inc.

**14.5      Assignment**. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither Halo nor Client may assign any of its rights or delegate any of its obligations under this Agreement , in whole or in part, except with the other's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. If Halo or Client desires to assign this Agreement, it shall give written notice to the other with sufficient detail to enable the other to properly consider the matter, and any assignee reasonably acceptable to the other shall be required to covenant in writing with such party(ies) to be bound by the terms of this Agreement. In the event Halo or Client consents to the delegation of any of the other's obligations under this Agreement, the delegating party shall remain responsible for any breach of this Agreement by any such delegate. Notwithstanding the foregoing, either Halo or Client may assign this Agreement in its entirety or delegate any portion of its obligations without the other's consent, but subject to prior written notice, to any of its Affiliates or to a successor to or purchaser of all or substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement .

**14.6      Construction**.

(a)      Independent Contractors. The parties are independent contractors to one another and this Agreement shall not be construed to create between Halo and Client any other relationship such as, by way of example only, that of employer-employee, principal-agent, joint-venturers, partners or any similar relationship, the existence of which is expressly denied by the parties.

(b)      No Third Party Benefit or Right. Nothing in this Agreement shall confer or be construed as conferring on any Person other than the parties hereto any benefit or the right to enforce any express or implied term of this Agreement.

(c)      Entire Agreement. This Agreement (including its Schedules and any other attachments), together with the Quality Agreement, constitutes the full, complete, final and integrated agreement between and among the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof.

(d)      PMSA. The parties acknowledge and agree that the PMSA is terminated in all respects as of [\*\*\*\*]. For clarity, as of such termination, [\*\*\*\*] . In addition, the Parties acknowledge and agree [\*\*\*\*].

(e)      Other Terms. No terms, provisions or conditions of any purchase order, quote, proposal, invoice, or other business form or written authorization used by Client or Halo will have



any effect on the rights, duties or obligations of the parties under, or otherwise modify, this Agreement, regardless of any failure of Client or Halo to object to such terms, provisions, or conditions, except to the extent such document specifically refers to this Agreement, sets forth an express intent to override it, and is signed by all parties.

(f) Amendments. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of all parties to be effective, except to the extent otherwise expressly provided in this Agreement; *provided*, that the signature of any one Client entity shall be binding on all the Client entities.

(g) Waivers. Either Halo's or Client's failure to require the other to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

(h) Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct.

(i) Drafting Party. The language in this Agreement is to be construed in all cases according to its fair meaning. Halo and Client acknowledge that each of them and their respective counsel have reviewed and revised this Agreement and that any rule of construction, to the effect that any ambiguities are to be resolved against the drafting party are not to be employed in the interpretation of this Agreement.

(j) Divisions. The division of this Agreement into Articles, sections, subsections and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement as a whole (including any Schedules hereto) and not to any particular part, Section, Schedule or the provision hereof.

(k) Certain Terms. Whenever used in this Agreement, unless otherwise specified: (i) all monetary amounts are expressed in, and all references to "\$" or "Dollars" mean, the lawful currency of the United States of America; (ii) the word "include" (with its grammatical variations) mean "include, without limitation," "include but are not limited to", or words of similar import; (iii) the words "agree" or "written agreement" will not impose any obligation on Halo or Client to agree to any terms or to engage in discussions relating to such terms, except as such party may elect in such party's sole discretion; (iv) the word "days" means calendar days; (v) the words "copy" and "copies" include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply; and (vii) all references to the singular shall include the plural and vice versa.

(l) Schedules. The following Schedules are attached to, incorporated in and form part of this Agreement:



Schedule A - Product List & Manufacturing Services Fees  
*Attachment* : Preliminary Product Specifications  
Schedule B - Additional Services  
Schedule C - Form of Inventory Report  
Schedule D - Form of Annual Reconciliation Report  
Schedule E - Form of Exclusive Components Purchasing Summary  
Schedule F - Technical Dispute Resolution  
Schedule G - Client-Supplied Material  
Schedule H - Quality Agreement  
Schedule I - List of Territories  
Schedule J - IM Machines  
Schedule K - Existing Orders Qualifying as Additional Services

**14.7**            **Governing Law**. This Agreement shall be construed and enforced in accordance with the laws of the State of New Jersey and the laws of the United States applicable therein. The UN Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. \_

**14.8**            **Further Assurances**. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

**14.9**            **Execution in Counterparts**. This Agreement may be executed in two or more counterparts, by original or facsimile signature, 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** , the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

**HALO PHARMACEUTICAL, INC.**

by /s/ L. Lee Karras\_\_\_\_\_

Name: L. Lee Karras

Title: Chief Executive Officer

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[\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

23269823.3.BUSINESS

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**EGALET CORPORATION**

by /s/ Robert S. Radie

Name: Robert Radie

Title: President & CEO

**EGALET LTD.**

by /s/ Robert S. Radie

Name: Robert Radie

Title: President & CEO

**EGALET US INC.**

by /s/ Robert S. Radie

Name: Robert Radie

Title: President & CEO

## **SCHEDULE A**

### **PRODUCT LisT & manufacturing services FEES**

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**SCHEDULE B**  
**additional SERVICES**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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**SCHEDULE C**  
**FORM OF INVENTORY REPORT**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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**SCHEDULE D**  
**FORM OF ANNUAL RECONCILIATION REPORT**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## **SCHEDULE E**

### **FORM OF exclusive components purchasing summary**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## SCHEDULE F

### technical dispute resolution

Any Technical Dispute that cannot be resolved by negotiation as provided in Sections 13.1 and 13.2 shall be resolved in the following manner:

1. **Appointment of Expert**. Within [\*\*\*\*\*] after a party requests pursuant to Section 13.2 that an expert be appointed to resolve a Technical Dispute, the parties shall jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the Technical Dispute. If the parties are unable to so agree within such [\*\*\*\*\*] period, or in the event of disclosure of a conflict by an expert pursuant to paragraph 2 below which results in the parties not confirming the appointment of such expert, then an expert (willing to act in that capacity hereunder) shall be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any individual appointed as an expert shall be entitled to act and continue to act as such notwithstanding that at the time of such appointment or at any time before giving a determination, the expert has or may have some interest or duty that conflicts or may conflict with the appointment; *provided*, that before accepting such appointment (or as soon as practicable after becoming aware of the conflict or potential conflict) the individual fully discloses any such interest or duty and the parties after such disclosure shall have nevertheless confirmed or re-confirmed the appointment.

3. **Not Arbitrator**. No expert shall be deemed to be an arbitrator and the provisions of the American Arbitration Act and no Applicable Law (including the American Arbitration Act) shall apply to any such expert or the expert's determination or the procedure by which the expert reaches a determination to be made pursuant to this Schedule.

4. **Procedure**. Where an expert is appointed:

(a) **Timing**. The expert shall be so appointed on condition that (i) the expert promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and issues such authorizations to the parties and any relevant Third Party for the proper conduct of a determination and any hearing and (ii) the expert renders a decision (with full reasons) within [\*\*\*\*\*] (or such other date as the parties and the expert may agree) after receipt of all information requested by the expert pursuant to paragraph 4(b) hereof.

(b) **Disclosure of Evidence**. The parties undertake to provide to the expert all such evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the Technical Dispute, which they shall disclose promptly and in any event within [\*\*\*\*\*] of a written request from the expert.

[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

(c) Advisors. Each party may appoint such counsel, consultants and advisors as it feels appropriate to assist the expert in making a determination and so as to present their respective cases so that at all times the parties shall co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in paragraph 4(a) above the expert shall not have rendered a decision in accordance with the appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert shall thereupon cease for the purposes of determining the Technical Dispute, save that if the existing expert renders a decision with full reasons prior to the appointment of the new expert, then such a decision shall have effect and the proposed appointment of the new expert shall be withdrawn.

(e) Final and Binding. The determination of the expert shall, save in the event of fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party shall bear its own costs in connection with any Technical Dispute to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert shall be shared equally by the parties.

*For the avoidance of doubt, nothing in this Schedule is intended to or shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether any Product is to be released for sale or distribution.*

## **SCHEDULE G**

### **Client supplied material**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## **SCHEDULE H**

### **quality agreement**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## **SCHEDULE I**

### **List of Territories**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## **SCHEDULE J**

### **IM Machines**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

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## **SCHEDULE K**

### **Halo Work Orders and Egalet Purchase Orders Existing as of the Effective Date Qualifying as Additional Services**

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[\*\*\*\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.

23269823.3.BUSINESS

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**Certification of Principal Executive Officer of Egalet Corporation  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Robert S. Radie, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Egalet Corporation;
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 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. 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
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 10, 2017

/s/ ROBERT S. RADIE

Robert S. Radie  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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**Certification of Principal Financial and Accounting Officer of Egalet Corporation  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Stanley J. Musial, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Egalet Corporation;
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 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. 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
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 10, 2017

/s/ STANLEY J. MUSIAL

Stanley J. Musial

Chief Financial Officer (Principal Financial Officer)

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**Certification Of  
Principal Executive Officer  
Pursuant To 18 U.S.C. Section 1350,  
As Adopted Pursuant To  
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with the Quarterly Report of Egalet Corporation (the "Company") on Form 10-Q for the period ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert S. Radie, president and chief executive officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 10, 2017

/s/ ROBERT S. RADIE

*President and Chief Executive Officer*  
*(Principal Executive Officer)*

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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**Certification Of  
Principal Financial and Accounting Officer  
Pursuant To 18 U.S.C. Section 1350,  
As Adopted Pursuant To  
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with the Quarterly Report of Egalet Corporation (the "Company") on Form 10-Q for the period ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stanley J. Musial, chief financial officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Dated: May 10, 2017

/s/ STANLEY J. MUSIAL

*Chief Financial Officer (Principal Financial Officer)*

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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