GALECTIN THERAPEUTICS INC Form S-3 December 21, 2015 Table of Contents

As filed with the Securities and Exchange Commission on December 21, 201

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

GALECTIN THERAPEUTICS INC.

(Name of Registrant as specified in its charter)

Nevada (State or other jurisdiction

04-3562325 (IRS Employer

of incorporation) Identification No.) 4960 Peachtree Industrial Blvd., Suite 240

Norcross, Georgia 30071

(678) 620-3186

(Address and telephone number of principal executive offices and principal place of business)

Peter G. Traber, M.D.

Chief Executive Officer and President

Galectin Therapeutics Inc.

4960 Peachtree Industrial Blvd., Suite 240

Norcross, Georgia 30071

(678) 620-3186

(Name address and telephone number of agent for service)

Copies to:

Robert E. Tritt

Dentons US LLP

303 Peachtree Street

Atlanta, Georgia 30308

Tel No.: (404) 527-4990

Fax No.: (404) 527-8890

Approximate date of commencement of proposed sale of the securities to the public: From time to time, after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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. (Check one):

Large accelerated filer " Accelerated filer x

Non-accelerated filer " (Do not check if smaller reporting company) Smaller reporting company "

CALCULATION OF REGISTRATION FEE

Title of Securities	Amount To Be	Proposed Maximum Offering Price	00 0	Amount Of
To Be Registered	Registered(1)	Per Share(2)	Offering Price(2)	Registration Fee(2)
Common Stock, \$0.001 par value per share,				
issuable upon exercise of warrants to				
purchase shares of Common Stock	3,571,425	\$2.50	\$8,928,563	\$899.11
TOTAL				\$899.11

(1) In accordance with Rule 416 under the Securities Act of 1933, as amended (the Securities Act), this registration statement also shall register and be deemed to cover any additional shares of Common Stock of the Registrant

- which may be offered or become issuable to prevent dilution resulting from stock splits, stock dividends, or similar transactions.
- (2) Estimated solely for the purpose of calculation of the registration fee pursuant to Rule 457(g) under the Securities Act based on the higher of (i) the price at which the warrants may be exercised and (ii) the average of the high and low reported sales prices of the Registrant s Common Stock on the NASDAQ Capital Market on December 18, 2015.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 21, 2015

GALECTIN THERAPEUTICS INC.

3,571,425 Shares

of

Common Stock Issuable Upon Exercise of Warrants

The selling stockholders identified in this prospectus may offer and sell up to 3,571,425 shares of our common stock, par value \$0.001 (Common Stock), which shares are issuable to the selling stockholders identified herein, at any time on or after May 25, 2016, upon exercise of warrants held by such selling stockholders (Warrants) at an exercise price of \$2.50 per share in connection with a registered direct offering that closed on November 25, 2015.

The selling stockholders may offer the shares of Common Stock issuable upon exercise of the outstanding Warrants from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

For information regarding the selling stockholders and the times and manner in which they may offer or sell the shares, see Selling Stockholder or Plan of Distribution.

We will not receive any of the proceeds from the sale of the Common Stock by the selling stockholders; however, we will receive the proceeds of any Common Stock we sell to the selling stockholders upon a cash exercise of the Warrants. We will pay the expenses of registering the Common Stock. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale of the Common Stock by the selling stockholders.

Our Common Stock is quoted on the NASDAQ Capital Market under the symbol GALT. On December 18, 2015, the last reported closing price for our Common Stock on the NASDAQ Capital Market was \$1.70 per share.

Investing in shares of our Common Stock involves certain risks. See <u>Risk Factors</u> beginning on page 4 of this prospectus. In addition, see <u>Risk Factors</u> in our Annual Report on Form 10-K for the year ended December 31, 2014 and supplemented by our Forms 10-Q for the periods ended March 31, 2015, June 30, 2015 and September 30, 2015, each of which has been filed with the Securities and Exchange Commission and is incorporated by reference into this prospectus. You should carefully read and consider these risk factors before you invest in shares of our Common Stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is December 21, 2015.

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ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption Selling Stockholders, from time to time, of up to 3,571,425 shares of our Common Stock, par value \$0.001 per share, issuable upon exercise of the Warrants. As of the date of this prospectus, none of the Warrants are exercisable by the selling stockholders. The Warrants will become exercisable beginning on May 25, 2016. We are not selling any shares of Common Stock under this prospectus and will not receive any proceeds from the sale of shares of Common Stock by the selling stockholders.

This prospectus is part of a registration statement we filed with the Securities and Exchange Commission (the SEC). Under this registration process, the selling stockholders may, from time to time, offer and sell up to 3,571,425 shares of our Common Stock, as described in this prospectus, in one or more offerings as described in the Plan of Distribution. This prospectus provides you with a general description of the securities the selling stockholders may offer. You should read this prospectus carefully before making an investment decision.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under Where You Can Find More Information and Important Information Incorporated By Reference before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein or therein is accurate as of any date other than the date on the front of those documents. Our business, financial

condition, results of operations and prospects may have changed since those dates.

As used in this prospectus, Galectin Therapeutics, the Company, we, our and similar terms refer to Galectin Therapeutics Inc. and its subsidiaries, unless the context indicates otherwise.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our securities. Before deciding to invest in our securities, you should read this entire prospectus, including the discussion of Risk Factors and our consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Our Company

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant materials as starting material in manufacturing processes to create proprietary complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that largely bind and inhibit galectin proteins, particularly galectin-3, we are undertaking the focused pursuit of therapies for indications where galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires additional resources.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical development, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established several collaborative scientific discovery programs with leading experts in carbohydrate chemistry and characterization. These discovery programs are generally aimed at the targeted development of new carbohydrate molecules which bind galectin proteins and offer alternative options to larger market segments in our primary disease indications. We also have established a discovery program aimed at the targeted development of small molecules (non-carbohydrate) which bind galectin proteins and may afford options for alternative means of drug delivery (e.g., oral) and as a result expand the potential uses of our compounds. Another discovery program seeks to identify the molecular interactions of molecules with the galectin-receptor. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immune enhancement for cancer therapy as well as in both liver fibrosis and fatty liver disease. All of our proposed products are presently in development, including pre-clinical and clinical trials.

We were founded in July 2000 as Pro-Pharmaceuticals, Inc., a Massachusetts corporation. On April 25, 2001, DTR-Med Pharma Corp., or DTR, which was incorporated in Nevada on January 26, 2001, entered into a stock exchange agreement with Pro-Pharmaceuticals, Inc., whereby DTR acquired all of the outstanding shares of common stock of Pro-Pharmaceuticals, Inc. On May 10, 2001, DTR changed its name to Pro-Pharmaceuticals, Inc. and on June 7, 2001, the Massachusetts corporation was merged into the Nevada corporation. On May 26, 2011, Pro-Pharmaceuticals, Inc. changed its name to Galectin Therapeutics Inc. In October, 2012, we moved our headquarters to a suburb of Atlanta, GA to be closer to a center of discovery collaboration while maintaining a contract laboratory operation in the Boston area.

The primary focus of our Company is to use galectin inhibitors to block galectin-3 and treat organ scarring or fibrosis in the liver. In particular, we are focused on the treatment of advanced fibrosis and cirrhosis, which we estimate to have up to 6 million and 2 million patients, respectively, in the United States.

Description of Recent Developments

On May 11, 2015, we announced that we expect to commence our Phase 2 program with GR-MD-02 for the treatment of nonalcoholic steatohepatitis, or NASH, with advanced fibrosis and cirrhosis in the second quarter of 2015. Our Phase 2 program consists of studies in two different NASH fibrosis indications, the NASH-CX trial in patients with NASH cirrhosis and the NASH-FX trial in NASH patients with advanced fibrosis, but not cirrhosis. Our Phase 2 program is supported by data generated with GR-MD-02 in our Phase1b study along with preclinical work.

Our NASH-CX trial will enroll 156 patients with NASH cirrhosis and will evaluate 26 bi-weekly doses of 2 mg/kg of GR-MD-02 and 8 mg/kg of GR-MD-02 and placebo, with patients randomized 1:1:1. We have identified 45 study sites in North America, obtained central institutional review board, or IRB, approval, and are working to secure site IRB approvals and contracts necessary to begin enrolling subjects. The primary endpoint will be change in hepatic venous pressure gradient, or HVPG, compared with placebo, and now secondary endpoints will include fibrosis stage on biopsy as well as the percent of collagen on biopsy at one year of treatment, liver stiffness measurements as determined by FibroScan Score, metabolic capacity as measured by a breath test and progression of cirrhosis as determined by complications. Correlation of HVPG with liver biopsy will continue to be studied, as planned. Additionally, the HVPG and liver biopsy measurements will be correlated with non-invasive measurements of liver fibrosis and function including FibroScan and ¹³C-methacetin breath test as additional secondary endpoints along with monitoring of progression of cirrhosis as determined by complications.

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The first patients were enrolled in this study in June of 2015, with top-line data readout expected at the end of 2017. We submitted a special protocol assessment, or SPA, with the United States Food and Drug Administration, or FDA, and received very useful feedback for the design of the study and the overall development program. We will proceed with the trial as a Phase 2 program, rather than resubmit the SPA to attempt to obtain designation as a Phase 3 trial currently.

The NASH-FX study will be a shorter, four-month trial in 30 NASH patients with advanced fibrosis, but not cirrhosis, randomized 1:1 to either 9 bi-weekly doses of 8 mg/kg of GR-MD-02 or placebo. This study is entitled Phase 2 Study to Evaluate Non-Invasive Imaging Methods in Efficacy Assessment of GR-MD-02 for the Treatment of Liver Fibrosis in Patients With NASH With Advanced Fibrosis. The non-invasive assessments included in this trial include LiverMultiScan (a multi-parametric nuclear magnetic resonance imaging method developed by Perspectum Diagnostics) as the primary endpoint compared with magnetic resonance elastography and FibroScan as secondary endpoints. This study was initiated in September 2015 and will be performed at Brooke Army Medical Center in Fort Sam Houston in Texas, with top-line data readout in the second half of 2016.

In addition to the NASH fibrosis program, we have initiated an exploratory, open-label Phase 2a trial in patients with moderate-to-severe plaque psoriasis. This is based on the known increase in galectin-3 in the skin of psoriatic patients and a patient in the Phase 1 trial with psoriasis who had an apparent remission of psoriasis while receiving GR-MD-02. Determination of future development in this indication will depend on results of this exploratory study. We expect a top-line data readout from this study in the third quarter of 2016.

We are also supporting independent research with GR-MD-02 in combination with two commercial melanoma drugs, as preclinical research has shown our compound enhances the efficacy of these therapies with this mechanism of action. The American Cancer Society estimates that in the U.S., there would be approximately 73,000 new diagnoses of melanoma and approximately 9,900 deaths in 2015. A Phase 1b study with GR-MD-02 in combination with YERVOY® is ongoing, with successful completion of three patients in the first dosing group, and two patients enrolled in the second dosing group. Another, a Phase 1b study in combination with KEYTRUDA® is expected to be initiated during the first half of 2016. Preclinical work in mouse cancer models with GR-MD-02 added to checkpoint inhibitors shows a boost in anti-tumor immunity, a reduction in tumor size and increased survival, and we look forward to receiving human clinical data.

On May 14, 2015, we reported that in an open-label Phase 1 study with 8 mg/kg dose of GR-MD-02 and 2 mg/kg dose of midazolam there was no drug-drug interaction and no serious adverse events or drug-related adverse events were observed. This study was required by the FDA and the primary objective was to determine if single or multiple intravenous (IV) doses of GR-MD-02 affect the pharmacokinetics (PK) of midazolam. The secondary objective was to assess the safety and tolerability of GR-MD-02 when administered concomitantly with midazolam.

The lack of a drug interaction in this study will allow us to expand the number of patients eligible for its Phase 2 clinical trial. In addition, should GR-MD-02 be approved for marketing, the success of this study supports a broader patient population for the drug label.

The open-label Phase 1 study in normal healthy volunteer subjects tested a single dose of IV midazolam in the absence of GR-MD-02, following a single IV dose of GR-MD-02 and following three weekly IV doses of GR-MD-02. The four dosing periods were spaced one week apart, with midazolam PK determined in dosing periods one, two and four. A total of 17 subjects completed the study and met the primary endpoint of midazolam clearance when administered alone, compared with when administered with single and multiple doses of GR-MD-02. With completion of this study, the company does not anticipate further drug-drug interaction studies will be required in the development of GR-MD-02.

Corporate Information

Our principal executive offices are located at 4960 Peachtree Industrial Blvd., Suite 240, Norcross, Georgia 30071. Our telephone number is (678) 620-3186, fax number is (770) 864-1327 and our website address is www.galectintherapeutics.com. The information on our website is not incorporated by reference into this prospectus and should not be relied upon with respect to this offering.

Description of Recent Concurrent Registered Offering and Private Placement

On November 25, 2015, pursuant to a securities purchase agreement dated as of November 19, 2015 (the Purchase Agreement) with certain purchasers identified on the signature pages to the Purchase Agreement (the Selling Stockholders), we issued to certain purchasers identified under the heading Selling Stockholders in this prospectus (the Selling Stockholders), in a registered direct offering, an aggregate of 4,761,900 shares (the Shares) of our common stock, par value \$0.001 per share (Common Stock), at a negotiated purchase price of \$2.06 per share, for aggregate gross proceeds to the Company of \$9,809,514, before deducting fees to the placement agent and other estimated offering expenses payable by the Company (the Registered Offering). The Shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on March 21, 2014, and was declared effective on March 31, 2014 (File No. 333-194747) (the Registration Statement).

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Concurrently with the Registered Offering, on November 25, 2015, pursuant to the Purchase Agreement, we issued to the Selling Stockholders warrants to purchase an aggregate of 3,571,425 shares of Common Stock (each, a Warrant and collectively, the Warrants) at an exercise price of \$2.50 per share in a private placement transaction (the Private Placement), which Warrants become exercisable on May 25, 2016 (the six month anniversary of the date of issuance the Warrants) and will expire on May 25, 2021 (the fifth anniversary of the date that the Warrants initially become exercisable).

In connection with the Private Placement and pursuant to a Registration Rights Agreement, dated November 19, 2015 (the Registration Rights Agreement), between the Company and each of the Selling Stockholders, the Company is required to file a registration statement on Form S-3 within 30 calendar days of the closing of the offering to provide for the resale of the shares of Common Stock underlying the Warrants. We filed the registration statement on Form S-3, of which this prospectus is a part, to fulfill our contractual obligations under the Registration Rights Agreement entered into in connection with the Private Placement to provide for the resale by the Selling Stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, of up to 3,571,425 shares of Common Stock issuable upon exercise of the Warrants issued in the Private Placement. For so long as any of the Warrants remain exercisable and outstanding, we are obligated to use our best efforts to maintain a current and effective registration statement covering the issuance of the maximum number of shares of Common Stock issuable upon exercise of the Warrants.

Roth Capital Partners, LLC acted as the exclusive placement agent (the Placement Agent) for the Company, on a reasonable best efforts basis, in connection with the Registered Offering and Private Placement. A copy of the Placement Agency Agreement, dated as of November 20, 2015, by and between the Company and the Placement Agent (the Placement Agency Agreement). Pursuant to the Placement Agency Agreement, the Placement Agent will be entitled to a cash fee of 6.0% of the gross proceeds paid to the Company for the Registered Offering and Private Placement and reimbursement of certain out-of-pocket expenses.

The Offering

Common Stock offered by Selling Stockholders

Up to 3,571,425 shares of Common Stock issuable upon the exercise of Warrants issued to the Selling Stockholders.

Common Stock to be outstanding after the 32,292,569 shares of Common Stock. offering*

Terms of the offering

The Selling Stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of Common Stock offered by this prospectus from time to time on the NASDAQ Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The shares of Common Stock may be sold at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices.

Use of proceeds

We will receive the exercise price with respect to any Common Stock we issue to the Selling Stockholders upon the exercise of the Warrants, if exercised for cash, if at all. We intend to use any proceeds from the exercise of any of the Warrants for working capital and other general corporate purposes. There is no assurance that any of the Warrants will ever be exercised for cash, if at all. We will not receive any of the proceeds from a sale of any Common Stock offered pursuant to this prospectus and issued upon exercise of the Warrants that may be received by the Selling Stockholders.

NASDAQ Symbol

GALT

Risk Factors

The purchase of our Common Stock involves a high degree of risk. You should carefully review and consider the Risk Factors beginning on page 4.

* The number of shares of Common Stock to be outstanding after this offering is based on the actual number of shares outstanding as of December 15, 2015 (28,721,144 shares) and assumes the full exercise of the Warrants held by the Selling Stockholders.

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RISK FACTORS

Investing in shares of our Common Stock involves risk. Before making any investment decision, you should carefully consider the risk factors under the caption Risk Factors in our most recent annual report on Form 10-K for the year ended December 31, 2014, and our subsequent quarterly reports on Form 10-Q, which are incorporated by reference in this prospectus, as well as in any applicable prospectus supplement, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the Exchange Act). These risks could materially affect our business, results of operation or financial condition and affect the value of our Common Stock. Additional risks and uncertainties that are not yet identified may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment. You could lose all or part of your investment. For more information, see Where You Can Find More Information.

FORWARD-LOOKING STATEMENTS

Certain statements made herein that look forward in time or express management s expectations or beliefs with respect to the occurrence of future events are forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend, plan, believe and would. should. statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

our early stage of development;

we have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit;

our dependence on additional outside capital;

we may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates;

uncertainties related to any litigation, including shareholder class actions and derivative lawsuits filed;

uncertainties related to our technology and clinical trials;

we may be unable to demonstrate the efficacy and safety of our developmental product candidates in human trials:

we may be unable to improve upon, protect and/or enforce our intellectual property;

we are subject to extensive and costly regulation by the U.S. Food and Drug Administration (FDA) and by foreign regulatory authorities, which must approve our product candidates in development and could restrict the sales and marketing and pricing of such products;

competition and stock price volatility in the biotechnology industry;

limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports; and

other risks detailed herein and from time to time in our SEC reports, including our Annual Report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2014, and our subsequent SEC filings. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described above and in the Risk Factors section of our annual report on Form 10-K for the year ended December 31, 2014. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Except as required by law, we undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date of this prospectus or the respective dates of documents incorporated by reference herein or therein that include forward-looking statements.

This prospectus also contains estimates, projections and other information concerning our industry, the market and our business. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties.

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USE OF PROCEEDS

We will receive the exercise price with respect to any Common Stock we issue to the Selling Stockholders upon exercise of the Warrants, if exercised for cash. If all of the Warrants are exercised for cash, we will receive proceeds of approximately \$8,928,562.50. We, however, will not receive any of the proceeds from a sale of any Common Stock offered pursuant to this prospectus that is issued upon exercise of the Warrants that may be received by the Selling Stockholders.

The Selling Stockholders are entitled to exercise the Warrants on a cashless basis in certain circumstances. In the event that the holders exercise the Warrants on a cashless basis, then we will not receive any proceeds from the exercise of the Warrants. There can be no assurance that any of the Warrants will be exercised by the Selling Stockholders at all or that the Warrants will be exercised for cash rather than pursuant to the cashless exercise feature. To the extent the Warrants are exercised for cash, we currently intend to use all proceeds received upon a cash exercise of the Warrants for working capital and general corporate purposes.

In the event of a fundamental transaction, then the Company or any successor entity will pay at the holder s option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction, an amount of cash equal to the value of the Warrant as determined in accordance with the Black Scholes option pricing model.

We cannot predict when the Warrants will be exercised, and it is possible that exercise of the Warrants may not result in the issuance of any Common Stock.

DESCRIPTION OF FINANCING TRANSACTIONS

On November 25, 2015, pursuant to the Purchase Agreement, the Company issued the Shares and the Warrants to the Selling Stockholders (the 2015 Financing Transaction). The Shares were sold to the Selling Stockholders in the Registered Offering at a negotiated purchase price of \$2.06 per share, for aggregate gross proceeds to the Company of \$9,809,514, before deducting fees to the Placement Agent and other estimated offering expenses payable by the Company. In a concurrent Private Placement, the Company also issued the Warrants to the Selling Stockholders, which Warrants are exercisable for $\frac{3}{4}$ of a share of the Company s Common Stock for each Share purchased for cash in the Registered Offering. The Warrants will be exercisable beginning on May 25, 2016 (the six month anniversary of the date of issuance), at an exercise price of \$2.50 per share and will expire on May 25, 2021 (the fifth anniversary of the date that the Warrants initially become exercisable). The Shares were issued pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on March 21, 2014, and was declared effective on March 31, 2014 (File No. 333-194747). The Warrants and the shares of our Common Stock issuable upon the exercise of the Warrants were and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act.

Only the 3,571,425 shares of our Common Stock issuable to the Selling Stockholders upon exercise of the Warrants are covered by this prospectus.

DESCRIPTION OF WARRANTS

The following is a brief description of the terms of the Warrants. This summary does not purport to be complete in all respects. This description is subject to and qualified in its entirety by reference to the Warrants, a form of which has been filed with the SEC and is also available upon request from us, and the agreements underlying the 2015 Financing Transaction, which have also been filed with the SEC and are also available upon request from us.

The Warrants are exercisable for an aggregate of 3,571,425 shares of our Common Stock at an exercise price of \$2.50 per share. The Warrants will be exercisable beginning on May 25, 2016 (the six month anniversary of the date of issuance) and will expire on May 25, 2021 (the fifth anniversary of the date that the Warrants initially become exercisable) and must be exercised prior to such expiration date; thereafter, we will amend the registration statement of which this prospectus is a part to withdraw from registration any shares not issued upon exercise of the Warrants.

All of the Warrants are outstanding, and no additional Warrants will be issued. We will deliver shares of our Common Stock upon exercise of a Warrant, in whole or in part. We will not issue fractional shares. Each Warrant contains instructions for exercise. With respect to cash exercises of the Warrants, the holders of the Warrants may exercise the Warrants at any time by delivering to us a written notice of exercise and payment of an amount equal to the exercise price multiplied by the number of shares of Common Stock as to which the Warrant is being exercised. Upon receipt of the notice of exercise and payment, we will issue and deliver to the holder the number of shares of our Common Stock to which the holder is entitled pursuant to the exercise.

Subject to the exclusions and limitations set forth in the Purchase Agreement and accompanying Warrants, the exercise price is subject to adjustment in the event we, at any time after the issuance date of the Warrants, pay a stock dividend on, subdivide or combine one or more classes of our then-outstanding shares of Common Stock. To date, the Warrants have been subject to no such price adjustment.

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The terms of the 2015 Financing Transaction include a beneficial ownership limitation applicable to the exercise of the Warrants, such that no holder may exercise the Warrants if, after such conversion or exercise, the holder would beneficially own individually, or together with its affiliates, more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise (the Beneficial Ownership Limitation); *provided, however*, that upon 61 days prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us. In addition, the holders of the Warrants will have the right to participate in any rights offering or distribution of assets (such as a spinoff) together with the holders of our Common Stock on an as-exercised basis.

For so long as any of the Warrants remain exercisable and outstanding, we are obligated to use our best efforts to maintain a current and effective registration statement covering the issuance of the maximum number of shares issuable upon exercise of the Warrants. If at any time after May 25, 2016, there is no effective registration statement registering, or no current prospectus available for, the resale of the Common Stock underlying the Warrants, then the Warrants may be exercised, in whole or in part, at such time by means of a cashless exercise.

DIVIDEND POLICY

We have never declared or paid cash dividends on our Common Stock. We currently intend to retain any future earnings and do not expect to declare or pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of our capital stock and certain provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, copies of which are on file with the SEC as exhibits to previous SEC filings. See Where You Can Find More Information elsewhere in this prospectus for information on where you can obtain copies of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, which have been filed with and are publicly available from the SEC. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and applicable provisions of the Nevada Revised Statutes.

Common Stock

We currently have authorized 50,000,000 shares of Common Stock, par value \$0.001 per share. As of December 15, 2015, there were 28,721,144 shares of Common Stock outstanding. Holders of our Common Stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the Common Stock. All outstanding shares of our Common Stock are fully paid and non-assessable.

Voting Rights. The holders of our Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our board of directors. Our stockholders have no right to cumulate their votes in the election of directors.

Dividends. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our Common Stock are entitled to receive ratably those dividends declared from time to time by the board of directors. We have never declared or paid any cash dividends on our common stock, and we do not currently intend to pay any cash dividends on our Common Stock for the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our Common Stock will be at the discretion of our board of directors and will depend upon, among other factors, our financial condition, operating results, current and anticipated cash needs, plans for expansion and other factors that our board of directors may deem relevant.

Rights Upon Liquidation. Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our Common Stock are entitled to share ratably in assets remaining after payment of liabilities.

Anti-Takeover Effects of Certain Provisions of Nevada Law

Effect of Nevada Anti-takeover Statute. We are subject to Section 78.438 of the Nevada Revised Statutes, an anti-takeover law. In general, Section 78.438 prohibits a Nevada corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless

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prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. Section 78.439 provides that business combinations after the three year period following the date that the stockholder becomes an interested stockholder may also be prohibited unless approved by the corporation s directors or other stockholders or unless the price and terms of the transaction meet the criteria set forth in the statute.

Section 78.416 defines business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder or any other corporation which is an affiliate or associate of the interested stockholder;

any sale, transfer, pledge or other disposition of the assets of the corporation involving the interested stockholder or any affiliate or associate of the interested stockholder if the assets transferred have a market value equal to 5% or more of all of the assets of the corporation or 5% or more of the value of the outstanding shares of the corporation or represent 10% or more of the earning power of the corporation;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation with a market value of 5% or more of the value of the outstanding shares of the corporation;

the adoption of a plan of liquidation proposed by or under any arrangement with the interested stockholder or any affiliate or associate of the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder or any affiliate or associate of the interested stockholder; or

the receipt by the interested stockholder or any affiliate or associate of the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 78.423 defines an interested stockholder as any entity or person beneficially owning, directly or indirectly, 10% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

Control Share Acquisitions. Sections 78.378 through 78.3793 of the Nevada Revised Statutes limit the voting rights of certain acquired shares in a corporation. The provisions apply to any acquisition of outstanding voting securities of a Nevada corporation that has 200 or more stockholders, at least 100 of which are Nevada residents, and conducts business in Nevada (an issuing corporation) resulting in ownership of one of the following categories of an issuing corporation s then outstanding voting securities: (i) twenty percent or more but less than thirty-three percent; (ii) thirty-three percent or more but less than fifty percent; or (iii) fifty percent or more. The securities acquired in such acquisition are denied voting rights unless a majority of the security holders approve the granting of such voting

rights. Unless an issuing corporation s articles of incorporation or bylaws then in effect provide otherwise: (i) voting securities acquired are also redeemable in part or in whole by an issuing corporation at the average price paid for the securities within 30 days if the acquiring person has not given a timely information statement to an issuing corporation or if the stockholders vote not to grant voting rights to the acquiring person s securities, and (ii) if outstanding securities and the security holders grant voting rights to such acquiring person, then any security holder who voted against granting voting rights to the acquiring person may demand the purchase from an issuing corporation, for fair value, all or any portion of his securities. These provisions do not apply to acquisitions made pursuant to the laws of descent and distribution, the enforcement of a judgment, or the satisfaction of a security interest, or made in connection with certain mergers or reorganizations.

Preferred Stock

We are currently authorized to issue 20,000,000 shares of undesignated stock, par value \$0.01 per share, the rights and privileges of which may be established from time to time by our board of directors. As of the date of this prospectus, our board of directors has designated:

5,000,000 as Series A 12% Convertible Preferred Stock, or Series A Preferred Stock, of which 1,402,500 are issued and outstanding as of the date of this prospectus;

900,000 as Series B-1 Convertible Preferred Stock, or Series B-1 Preferred Stock, and 2,100,000 as Series B-2 Convertible Preferred Stock, referred to together as the Series B Preferred Stock, all of which are issued and outstanding as of the date of this prospectus; and

1,000 as Series C Super Dividend Convertible Preferred Stock, or Series C Preferred Stock, of which 176 are issued and outstanding as of the date of this prospectus.

Series A Preferred Stock

The shares of Series A Preferred Stock accrue interest at 12% per annum payable at our option in cash or shares of common stock valued per share at the higher of \$6.00 or 100% of the value weighted average price of our shares of common stock for the 20 consecutive trading days prior to the applicable dividend payment date. Holders are entitled to vote as a class with the

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common stock and each share of Series A Preferred Stock is convertible at any time to one-sixth share of common stock, subject to adjustment in the event of a stock dividend, stock split or combination, reclassification or similar event. We may require conversion if the closing price of the common stock exceeds \$18.00 for 15 consecutive trading days and a registration statement covering the resale of the shares of common stock issuable upon conversion of the Series A Preferred Stock is then in effect.

Series B Preferred Stock

Dividends. Holders of the Series B will be entitled to receive cumulative dividends at the rate of 12% per share per annum (compounding monthly) payable quarterly which may, at our option, be paid in cash or common stock. Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, we amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to provide that dividends are payable in cash or shares of Common Stock valued at 100% of the volume weighted average price of the Common Stock for the 20 consecutive trading days prior to the dividend payment date on and after September 30, 2011. If we do not pay any dividend on the Series B, dividends will accrue at the rate of 15% per annum (compounding monthly).

Conversion Rights. Each share of Series B is convertible into two-thirds (approximately 0.667) shares of Common Stock at the conversion price of \$3.00 per share at the option of (i) the holder, at any time and (ii) us, at any time after February 12, 2010 (and upon 10 days notice) if the Common Stock was quoted at or above \$9.00 for 15 consecutive trading days and an effective registration statement regarding the underlying shares of common stock is in effect (subject to certain monthly volume limits). Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, we amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to remove our right to compel conversion of the Series B Preferred Stock to shares of its Common Stock.

Redemption Rights. Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, we amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to provide that, upon notice of not less than 30 trading days, a holder of Series B may require us to redeem, in whole or in part at any time on or after the earlier of (a) February 12, 2019 or (b) the date of issuance of a promissory note to David Platt in connection with the achievement of certain milestones under his separation agreement.

The redemption price will be equal to the sum of the stated value of the Series B, plus all accrued but unpaid dividends thereon, as of the redemption date. If we fail to pay the redemption price in cash on the redemption date, then the holders of the Series B requesting redemption may, at their sole option, automatically convert their shares of Series B into a promissory note bearing interest at the rate of 15% per year and secured by a lien on all of our assets. So long as any shares of the Series B remain outstanding, we are also subject to restrictions limiting, among other things, amendments to our organizational documents; the purchase or redemption of our capital stock; mergers, consolidations, liquidations and dissolutions; sales of assets; dividends and other restricted payments; investments and acquisitions; joint ventures, licensing agreements, exclusive marketing and other distribution agreements; issuances of securities; incurrence of indebtedness; incurrence of liens and other encumbrances and issuances of any common stock equivalents.

Voting Rights. Except as noted below, the holder of each share of Series B shall be entitled to the number of votes equal to the number of shares of Common Stock into which such share of Series B would be convertible, and shall otherwise have voting rights and powers equal to the voting rights and powers of the Common Stock. With respect to the election of directors, the holders of the Series B shall vote together as a separate class to elect three (3) members of

the Board of Directors (the Series B Directors), and we shall take all reasonably necessary or desirable actions within its control (including, without limitation, calling special meetings of the Board of Directors, nominating such persons designated by the holders of the Series B as directors on the applicable proxy statements and recommending their election) to permit the holders of the Series B to appoint two additional (2) members of the Board of Directors (the Series B Nominees), who shall be subject to election by all shares our voting stock voting together as a single group, until such time as all authorized shares of Series B have has been issued and sold, after which the number of Series B Nominees shall be three (3), and shall remain three (3) until there are no longer any shares of Series B outstanding. The holders of Series B shall vote together with the holders of Common Stock and other voting capital stock to elect all other members of the Board of Directors.

Other Restrictions. So long as any shares of the Series B remain outstanding, we may not, without the approval of the holders of a majority of the shares of Series B outstanding, among other things, (i) change the size of our Board of Directors; (ii) amend or repeal our Articles of Incorporation or Bylaws or file any articles of amendment designating the preferences, limitations and relative rights of any series of preferred stock; (iii) create or increase the authorized amount of any additional class or series of shares of stock that is equal to or senior to Series B; (iv) increase or decrease the authorized number of shares of the Series B; (v) purchase, redeem or otherwise acquire for value any shares of any class of capital stock; (vi) merge or consolidate our into or with any other corporation or sell, assign, lease, pledge, encumber or otherwise dispose of all or substantially all of our assets or those of any subsidiary; (vii) voluntarily or involuntarily liquidate, dissolve or wind up our or our business; (viii) pay or declare dividends on any capital stock other than the preferred stock, unless the Series B share ratably in such dividend and all accrued dividends payable with respect to the Series B have been paid prior to the payment or declaration of such dividend; (ix) acquire an equitable interest in, or the assets or business of any other entity in any form of transaction; (x) create or commit us to enter into a joint venture, licensing agreement or exclusive marketing or other distribution agreement with respect to our products, other than in the ordinary course of business; (xi) permit us or any subsidiary to sell or issue any security of such

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subsidiary to any person or entity other than ours; (xii) enter into, create, incur, assume or guarantee any indebtedness for borrowed money of any kind (other than indebtedness existing on the initial closing date and approved by Series B shareholders); (xiii) enter into, create, incur or assume any liens of any kind (other than certain permitted liens); (xiv) issue any common stock equivalents; (xv) increase the number of shares of our common stock that may be issued pursuant to options, warrants or rights to employees, directors, officers, consultants or advisors above 250,000.

Series C Super Dividend Preferred Stock

Conversion Rights. Each holder of Series C may convert all, but not less than all, of his Series C shares plus accrued and unpaid dividends into Common Stock at the price of \$6.00 per share of Common Stock (Conversion Price), such that approximately 1,667 shares of Common Stock will be issued per each converted share of Series C (accrued and unpaid dividends will be issued as additional shares). At September 30, 2015, the 176 outstanding shares of Series C were convertible into a total of approximately 293,392 shares of Common Stock.

Subject to the continuing obligation to pay post conversion dividends, we may convert all, but not less than all, of the Series C (plus all accrued and unpaid dividends) into Common Stock, at the Conversion Price, upon such time that the closing price of the Common Stock is no less than \$18.00 per share for 15 consecutive trading days.

Dividends. Holders of Series C shall be entitled to receive cumulative non-compounding dividends at the rate per share of Series C equal to the greater of (i) 6% per annum of the Stated Value (also defined as the Floor) or (ii) 2.5% of net sales until the total dividends paid is equal to the initial investment and 1.25% of net sales thereafter. The maximum amount each Series C shareholder will receive in dividend payments is equal to \$100,000 (the Maximum Payout). For purposes of this dividend calculation, net sales shall mean gross revenues actually received by us, from the sale or licensing of the product DAVANAT® (GM-CT-01), less chargebacks, returns, expenses attributable to product recalls, duties, customs, sales tax, freight, insurance, shipping expenses, allowances and other customary deductions.

The dividend shall be payable in arrears semiannually on March 31 and September 30, beginning with the first such date after the original issue date; provided, however, that all dividends and all other distributions shall cease, and no further dividends or other distributions shall be paid, in respect of each share of Series C from and after such time that the Maximum Payout has been paid in respect of such share of Series C. Such dividends shall be payable at the Company s option either in cash or in duly authorized, fully paid and non-assessable shares of Common Stock valued at the higher of (i) \$3.00 per share or (ii) the average of the Common Stock trading price for the ten (10) consecutive trading days ending on the trading day that is immediately prior to the dividend payment date.

Series C Post Conversion Dividend Right. In the event that any share of Series C is converted into Common Stock before the Maximum Payout is paid in respect of such converted share of Series C, then the holder shall have the right to continue to receive dividends in respect of such converted share of Series C equal to the remaining payout (the Series C Preferred Stock Post Conversion Dividend Right) which shall be equal to the Maximum Payout less the cumulative dividends received through the conversion date. One share of Series C Preferred Stock Post Conversion Dividend Right shall be issued for each such converted share of Series C. The holder of each Series C Preferred Stock Post Conversion Dividend Right shall receive the remaining payout on an equal basis and in conjunction with the then outstanding shares of Series C and all the other then outstanding Series C Post Conversion Dividend Rights, in the same manner and subject to the same terms and conditions as applicable to the payment of dividends on each share of Series C, except that for purposes of calculating the dividend the Floor shall not apply. The Series C Preferred Stock Post Conversion Dividend Right shall have no stated value, liquidation preference or right to any dividends or distributions other than the remaining payout. The Series C Preferred Stock Post Conversion Right is subject to redemption in the same manner as outstanding Series C shares.

Liquidation Rights. In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the holders of Series C will receive \$10,000 per share plus accrued and unpaid dividends, payable prior and in preference to any distributions to the holders of Common Stock but after and subordinate to the Series A 12% Convertible Preferred Stock (Series A), Series B-1 and Series B-2, subject to the Maximum Payout.

Redemption. Upon a sale of the Company, we shall redeem all of the then outstanding shares of Series C and Series C Preferred Stock Post Conversion Rights within thirty (30) days after the transaction constituting the sale of the Company is closed and such closing is fully funded. The price to redeem a share of Series C and each redeemed Series C Preferred Stock Post Conversion Redemption Right shall be equal to (i) (A) the applicable return on investment (ROI) percentage, multiplied by (B) \$10,000, minus (ii) the cumulative dividends received through the redemption date. The redemption price shall be payable at our option either in cash or in shares of common stock valued at the higher of (i) \$3.00 per share or (ii) the average market price for the ten consecutive trading days ending immediately prior to the date of redemption. The ROI Percentage shall mean the percentage that applies as of the redemption date, as follows:

ROI Percentage

200%	before the second anniversary of the date of issuance;
250%	on or after the second anniversary of the date of issuance, but before the third anniversary of the date of
	issuance;
300%	on or after the third anniversary of the date of issuance, but before the fourth anniversary of the date of issuance;
350%	on or after the fourth anniversary of the date of issuance, but before the fifth anniversary of the date of issuance;
400%	on or after the fifth anniversary of the date of issuance, but before the sixth anniversary of the date of issuance;
450%	on or after the sixth anniversary of the date of issuance, but before the seventh anniversary of the date of issuance;
500%	on or after the seventh anniversary of the date of issuance, but before the eighth anniversary of the date of issuance; and
550%	on or after the eighth anniversary of the date of issuance, but before the ninth anniversary of the date of issuance.

Voting Rights. The Series C shares have no voting rights.

Transfer Agent and Registrar. The transfer agent and registrar for any series or class of preferred stock will be set forth in the applicable prospectus supplement.

Except for shares of Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock, there are no other shares of preferred stock outstanding as of the date of this prospectus.

SELLING STOCKHOLDERS

The Common Stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders upon exercise of the Warrants. For additional information regarding the issuances of those shares of Common Stock and Warrants, see Description of Recent Concurrent Registered Offering and Private Placement above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder, based on its ownership of the shares of Common Stock and Warrants, as of December 15, 2015, assuming exercise of the Warrants held by the Selling Stockholder on that date, without regard to any limitations on exercises.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of the Registration Rights Agreement with the Selling Stockholders, this prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon exercise of the related Warrants, determined as if the outstanding Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Registration Rights Agreement, without regard to any limitations on the exercise of the Warrants. The fourth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

Under the terms of the Warrants, a Selling Stockholder may not exercise the Warrants to the extent such exercise would cause such Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of the Warrants which have not been exercised (the Beneficial Ownership Limitation); provided, however, that upon prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us. The number of shares in the second column does not reflect this limitation. The Selling Stockholders may sell all, some or none of their shares in this offering. See Plan of Distribution.

	Number of shares of Common Stock Owned Prior to	Maximum Number of shares of Common Stock to be Sold Pursuant to this	Number of shares of Common Stock Owned After	Percentage of Ownership After
Name of Selling Stockholder (1)	Offering $(1)(2)$	Prospectus (3)	Offering	Offering
Sabby Healthcare Master Fund, Ltd. (4)	1,101,864	826,398	1,101,864	3.41%
Sabby Volatility Warrant Master Fund, Ltd. (5)	485,436	364,077	485,436	1.50%
Empery Asset Master Ltd (6)	518,518	469,886	518,518	1.61%
Empery Tax Efficient, LP (7)	335,022	303,599	335,022	1.04%
Empery Tax Efficient II, LP (8)	460,149	416,990	460,149	1.42%
CVI Investments, Inc. (9)	1,587,300	1,190,475	1,587,300	4.92%

- (1) This table and the information in the notes below are based upon information supplied by the Selling Stockholders. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock that can be acquired under options or warrants that are currently exercisable, or which will become exercisable no later than 60 days after December 15, 2015, are deemed outstanding for the purposes of computing the percentage of the person holding such options or warrants, but not deemed outstanding for the purposes of computing the percentage of any other person. Except as indicated by footnote and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown beneficially owned by them.
- (2) Excludes shares issuable pursuant to the Warrants.
- (3) The actual number of shares of Common Stock offered hereby and included in the registration statement of which this prospectus forms a part includes, in accordance with Rule 416 under the Securities Act, such indeterminate number of additional shares of our Common Stock as may become issuable in connection with any proportionate adjustment for any stock splits, stock combinations, stock dividends, recapitalizations or similar events with respect to Common Stock.
- (4) Sabby Management, LLC is the investment manager of Sabby Healthcare Master Fund, Ltd. (Sabby HMF) and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby HMF. Each of Sabby Management, LLC and Hal Mintz disclaims