

Section 1: 424B4 (FORM 424B4)

Filed Pursuant to Rule 424(b)(4)
Registration Statement No. 333-234234

PROSPECTUS

Diffusio₂n

Pharmaceuticals Inc.

**5,104,429 Class A Units consisting of Shares of Common Stock and Series I Warrants and Series II Warrants or
6,324,143 Class B Units consisting of Pre-Funded Warrants and Series I Warrants and Series II Warrants
11,428,572 Shares of Common Stock underlying the Series I Warrants
11,428,572 Shares of Common Stock underlying the Series II Warrants**

We are offering 5,104,429 Class A Units with each Class A Unit at a public offering price of \$0.35 per Class A Unit consisting of one share of our common stock, one Series I Warrant to purchase one share of our common stock and one Series II Warrant to purchase one share of our common stock. The Class A Units will not be certificated and the share of common stock, the Series I Warrant and Series II Warrant comprising such unit are immediately separable and will be issued separately in this offering.

We are also offering to certain purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) or otherwise at such purchaser's election, 6,324,143 Class B Units, with each Class B Unit consisting of one pre-funded warrant to purchase one share of our common stock, or a pre-funded warrant, one Series I Warrant to purchase one share of our common stock and one Series II Warrant to purchase one share of our common stock. The purchase price of each Class B Unit will be equal to the price at which a Class A Unit is sold to the public in this offering, minus \$0.001, and the exercise price of each pre-funded warrant will be \$0.001 per share. The Class B Units will not be certificated and the pre-funded warrant, the Series I Warrant and Series II Warrant comprising such unit are immediately separable and will be issued separately in this offering. Each purchase of Class B Units in this offering will reduce the number of Class A Units in this offering on a one-for-one basis. Therefore the number of Series I Warrants and Series II Warrants sold in this offering will not change as a result of a change in the mix of the Class A Units sold and Class B Units Sold. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full.

Each Series I Warrant will have an exercise price of \$0.35 per share of common stock, will be exercisable upon issuance and will expire eighteen months from the date of issuance. Each Series II Warrant will have an exercise price of \$0.35 per share of common stock, will be exercisable upon issuance and will expire five years from the date of issuance.

Our common stock is listed on the Nasdaq Capital Market under the symbol "DFN." On November 12, 2019, the reported closing price per share of our common stock was \$0.55. There is no established public trading market for the pre-funded warrants, the Series I Warrants, the Series II Warrants and the Placement Agent's Warrants and we do not expect a market to develop. Without an active trading market, the liquidity of the warrants will be limited. In addition, we do not intend to list the pre-funded warrants, the Series I Warrants, the Series II Warrants or the Placement Agent's Warrants on the Nasdaq Capital Market, any other national securities exchange or any other trading system.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 7 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

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.

	Per Class A Unit (one share of common stock, one Series I Warrant and one Series II Warrant)	Per Class B Unit (one Pre-funded Warrant, one Series I Warrant and one Series II Warrant)	Total
Public offering price	\$ 0.35	\$ 0.349	\$ 3,993,676
Placement Agent's fees (1)	\$ 0.028	\$ 0.028	\$ 320,000
Proceeds, before expenses, to us (2)	\$ 0.322	\$ 0.321	\$ 3,673,676

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- (1) We have agreed to reimburse the placement agent for certain of its expenses. In addition, we have agreed to issue to the Placement Agent warrants to purchase up to 571,429 shares of our common stock. See "Plan of Distribution" for additional information and a description of the compensation payable to the Placement Agent.
- (2) We estimate the total expenses of this offering payable by us, excluding the Placement Agent's fees, will be approximately \$376,000.

The securities are expected to be delivered to purchasers on or about November 15, 2019.

H.C. Wainwright & Co.

The date of this prospectus is November 13, 2019

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. You should not assume that the information in this prospectus is accurate at any date other than the date indicated on the cover page of this prospectus or the filing date of any document incorporated by reference, regardless of its time of delivery. We are offering to sell Class A Units and Class B Units and seeking offers to buy Class A Units and Class B Units only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the Class A Units and Class B Units.

For investors outside the United States: neither we nor the Placement Agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the Class A Units and Class B Units and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission (the “SEC”). As it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the “Risk Factors” and our financial statements and the related notes contained in and incorporated by reference into this prospectus, before purchasing our securities in this offering. Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to “Diffusion,” “we,” “our,” “us” or similar references mean Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc.

Business Overview

We are a clinical stage biotechnology company developing new treatments for life-threatening conditions by improving the body’s ability to bring oxygen to the areas where it is needed most. We are developing our lead product candidate, transcrocetinate sodium, also known as trans sodium crocetininate (“TSC”), for use in those life-threatening conditions in which cellular oxygen deprivation (“hypoxia”) is the basis for significant unmet medical needs. TSC is designed to safely and selectively target and re-oxygenate the micro-environment of hypoxic cells, and can potentially be used in many indications, including stroke, oncology and cardiovascular disease. In stroke, TSC helps promote the diffusion of oxygen into those brain cells in which oxygen-deprivation causes neuronal death resulting in patient mortality or morbidity. In cancer, TSC re-oxygenates treatment-resistant cancerous tissue, making the cancer cells up to three times more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy.

A range of tissue types, including both normal and cancerous cells, has been shown to be safely re-oxygenated in our preclinical and clinical studies using TSC’s novel mechanism of action. We believe TSC’s ability to re-oxygenate normal tissue that has become oxygen-deprived provides opportunities for new therapeutic approaches to conditions ranging from stroke and emergency medicine to cardiovascular and neurodegenerative diseases. In oncology, we believe TSC’s therapeutic potential is not limited to one specific tumor type, thereby making it potentially useful to improve standard-of-care treatments in many life-threatening cancers. Given TSC’s safety profile and animal data, we could, with appropriate funding, move directly into Phase 2 studies for TSC in many such cancers. The successful completion of trials for TSC or any other potential product candidate in these or any other indication is dependent upon our ability to further raise necessary capital.

We believe that TSC has potential applications in stroke and emergency medicine. A Phase 2 trial in cooperation with UCLA and the University of Virginia to test TSC in the treatment of acute stroke has received approval for enrollment by the FDA. We enrolled our first patient in the study in October 2019. This trial, which will feature in-ambulance dosing of TSC, is named the PreHospital Acute Stroke Therapy - TSC (PHAST - TSC) and is expected to enroll 160 patients, with 80 in the treatment arm and 80 in the control arm. We believe in-ambulance dosing of TSC could significantly cut the time in which the stroke-related oxygen deprivation to brain cells goes untreated, potentially leading to a better outcome for stroke victims treated in this manner. Subject to receipt of adequate funding to support the PHAST – TSC trial, we expect to receive data readout during the first half of 2021.

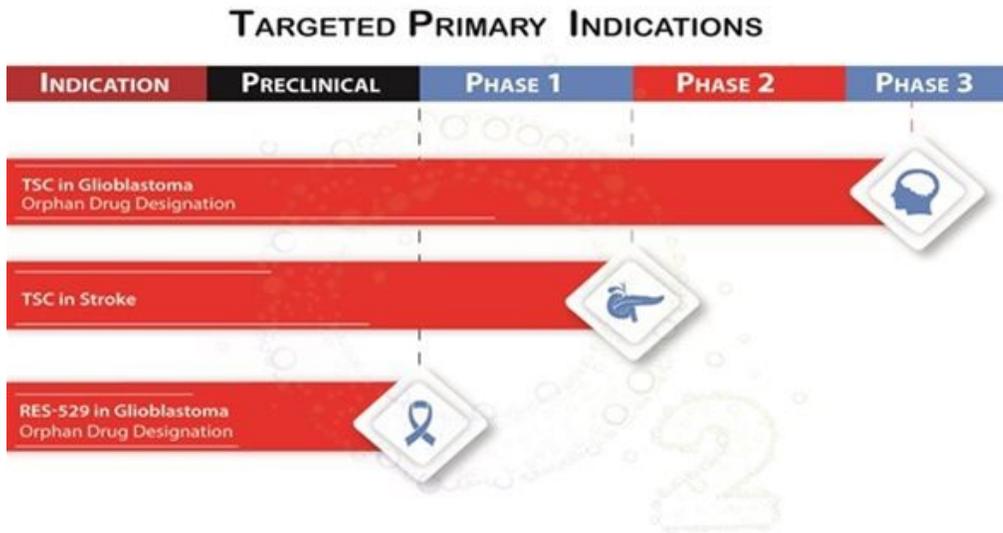
Our primary oncology program targets TSC against treatment-resistant brain cancer. A Phase 2 clinical program, completed in the second quarter of 2015, evaluated 59 patients with newly diagnosed glioblastoma multiforme (“GBM”), a particularly deadly form of primary brain cancer. GBM affects approximately 12,000 patients annually in the United States and approximately 35,000 patients annually worldwide. This open label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC when combined with GBM’s standard of care, including a 37% improvement in overall survival over the control group at two years. A particularly strong efficacy signal was seen in the inoperable patients, where survival of TSC-treated patients at two years was increased by almost four-fold over the controls. In December 2017, the Company initiated the INvestigation of TSC Against Cancerous Tumors (INTACT) Phase 3 trial in the newly diagnosed inoperable GBM patient population. The trial is designed to enroll 236 patients in total, with 118 in the treatment arm and 118 in the control arm.

The trial began with an open label 8 patient safety run-in for which enrollment has completed and is now closed. With the FDA’s permission, a total of 19 patients were enrolled to ensure 8 complete data sets. The INTACT Trial Data Safety Monitoring Board (DSMB) met in the third quarter of 2019 and recommended that the study be continued. The DSMB concluded that no adverse safety signal had been observed, and unanimously recommended continuing the study as planned using the highest tested dose of TSC – 1.5 mg/kg – during the adjuvant treatment chemotherapy period with temozolomide. Commencement of enrollment in the randomization portion of the INTACT Phase 3 Trial is contingent upon our entering into a strategic partnership providing the necessary resources to undertake the full trial.

In addition to the TSC programs, we are exploring alternatives regarding how best to capitalize upon our product candidate RES-529, which may include possible out-licensing and other options. RES-529 is a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase 1 clinical trials for age-related macular degeneration and was in preclinical development in oncology. RES-529 has shown activity in both in vitro and in vivo glioblastoma animal models and has been demonstrated to be orally bioavailable and capable of crossing the blood-brain barrier.

Summary of Current Product Candidate Pipeline

The following table, as of September 30, 2019, summarizes the targeted primary indications for Diffusion’s lead molecule, TSC, and RES-529:

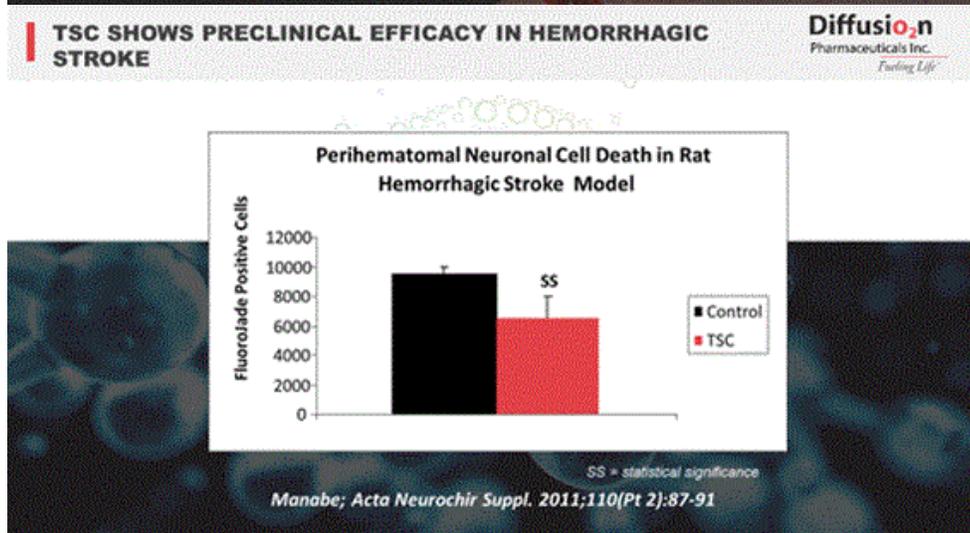
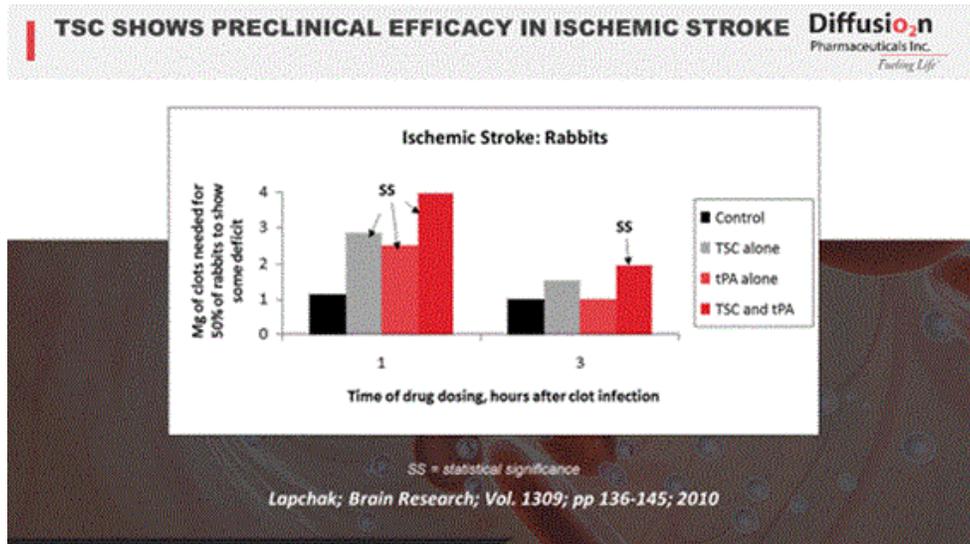


TSC Stroke Program

We believe that TSC has potential application as a treatment for stroke. Approximately 800,000 strokes occur in the United States each year, with an estimated annual cost of \$43.0 billion. The damage from a stroke begins immediately upon onset: brain cell death begins immediately at the onset of a stroke. A stroke can take a significant toll on its victims. Among long-term stroke survivors, approximately 66% of stroke patients end up needing mental or physical rehabilitation, approximately 40% are classified as moderately to severely disabled after the initial few days of recovery, and approximately 10% of stroke patients require long-term care.

We believe in-ambulance dosing of TSC could significantly cut the time in which the stroke-related oxygen deprivation to brain cells goes untreated, potentially leading to a better outcome for stroke victims treated in this manner. Half of all stroke patients are transported to hospitals by emergency medical services (EMS), such as ambulances, with estimates of up to 80% of all patients in urban and suburban areas being transported by EMS.

TSC has shown pre-clinical efficacy as a potential treatment for ischemic and hemorrhagic stroke in laboratory testing. Rabbits receiving TSC alone at one hour after developing a clot have shown a statistically significant positive response to treatment. Additionally, rabbits receiving TSC in conjunction with Tissue Plasminogen Activator (tPA) at three hours after developing a clot have shown a statistically significant positive response to treatment. Additionally, rats dosed with TSC in a hemorrhagic stroke showed a statistically significant decrease in damaged brain cells. The following charts provide additional detail on these animal studies:



Corporate Information

We are a Delaware corporation that was incorporated in June 2015. Prior to June 2015, we were a Nevada corporation. We maintain our principal executive offices at 1317 Carlton Avenue, Suite 200, Charlottesville, VA 22902. Our telephone number there is (434) 220-0718. The address of our website is www.diffusionpharma.com. The information set forth on, or connected to, our website is expressly not incorporated by reference into, and does not constitute a part of, this prospectus.

We are a “smaller reporting company” as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies in this prospectus as well as our filings under the Exchange Act.

THE OFFERING

Class A Units offered by us in this offering

We are offering 5,104,429 of Class A Units. Each Class A Unit consists of one share of our common stock, one Series I Warrant to purchase one share of our common stock and one Series II Warrant to purchase one share of our common stock. The Class A Units will not be certificated and the shares of common stock, Series I Warrants and Series II Warrants comprising such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon the exercise of the warrants included in the Class A Units.

Class B Units offered by us in this offering

We are also offering to those purchasers, whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of Class B Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering or otherwise at such purchaser's election, 6,324,143 Class B Units. Each Class B Unit consists of one pre-funded warrant to purchase one share of our common stock, or a pre-funded warrant, one Series I Warrant to purchase one share of our common stock and one Series II Warrant to purchase one share of our common stock. The purchase price for each Class B warrant would equal the per unit public offering price for the Class A Units in this offering less the \$0.001 per share exercise price of the pre-funded warrant part of the Class B Unit, and the exercise price of each pre-funded warrant would equal \$0.001 per share.

The Class B Units will not be certificated and the pre-funded warrant, Series I Warrant and Series II Warrant included in such unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of our common stock issuable upon exercise of the warrants included in the Class B Units and the pre-funded warrants.

For more information, see the section entitled "Description of Capital Stock" on page 15 of this prospectus.

Series I Warrants and Series II Warrants offered by us in this offering

Series I Warrants to purchase up to 11,428,572 shares, which may be exercised beginning on their date of issuance. The Series I Warrants are exercisable until the eighteen month anniversary of the original issuance date. The Series I Warrants have an exercise price of \$0.35 per share of common stock, subject to adjustment.

Series II Warrants to purchase up to 11,428,572 shares, which may be exercised beginning on their date of issuance. The Series II Warrants are exercisable until the five year anniversary of the original issuance date. The Series II Warrants have an exercise price of \$0.35 per share of common stock, subject to adjustment.

For more information, see the section entitled "Description of Capital Stock" on page 15 of this prospectus.

Common stock to be outstanding after this offering	16,121,862 shares, assuming the exercise in full of all pre-funded warrants issued in this offering.
Use of proceeds	We intend to use the net proceeds from this offering to fund research and development of our lead product candidate, TSC, including clinical trial activities, and for general corporate purposes. See “Use of Proceeds.”
Risk factors	You should read the “Risk Factors” section of this prospectus as well as all other information included in this prospectus, including the information in the documents incorporated by reference into this prospectus, for a discussion of certain of the factors to consider carefully before deciding to purchase any securities in this offering.
National Securities Exchange Listing	Our common stock is listed on the Nasdaq Capital Market under the symbol “DFFN.”

The number of shares of our common stock to be outstanding after this offering is based on 4,693,290 shares of common stock outstanding as of September 30, 2019 and excludes as of that date:

- 309,276 shares of common stock issuable upon the exercise of outstanding stock options under the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended (the “2015 Equity Plan”), at a weighted-average exercise price of \$55.78 per share;
- 3,469,825 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of \$15.09 per share; and
- 19,740 shares of common stock reserved for future issuance under the 2015 Equity Plan.

Unless otherwise indicated, all information contained in this prospectus assumes no sale of Class B Units, which, if sold, would reduce the number of Class A Units (and therefore the number of shares of common stock sold in this offering on a one-for-one basis) and no exercise of any warrants issued in this offering. Additionally, unless otherwise indicated, all share information contained in this prospectus reflects the completion on December 13, 2018, of a 1-to-15 reverse stock split (the “Reverse Stock Split”) of our common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would have been entitled to receive fractional shares of common stock had their holdings rounded up to the next whole share. Proportional adjustments were made to the Company’s outstanding warrants, stock options and other equity securities and to the 2015 Equity Incentive Plan, as amended, to reflect the Reverse Stock Split, in each case, in accordance with the terms thereof.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making your decision to invest in our securities. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows, and our future prospects would likely be materially and adversely affected. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. In addition, you should also carefully consider the other risks described under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated herein by reference, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein.

Risks Related to this Offering

We have significant discretion over the use of the net proceeds from this offering.

Our net proceeds from this offering are expected to be approximately \$3.3 million. We intend to use the net proceeds of this offering to fund research and development of our lead product candidate, TSC, including clinical trial activities, and for general corporate purposes. Accordingly, our management will have broad discretion as to the application of such proceeds. The proceeds shall be used to carry out our business plan, pay salaries to our employees, and satisfy all our expenses, foreseeable and unforeseeable. As is the case with any business, it should be expected that certain expenses unforeseeable to management at this juncture will arise in the future. There can be no assurance that management’s use of proceeds generated through this offering will prove optimal or translate into revenue or profitability for the Company. Investors are urged to consult with their attorneys, accountants and personal investment advisors prior to making any decision to invest in the Company.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years, if at all. Our net losses were approximately \$18.4 million and \$1.4 million for the years ended December 31, 2018 and 2017, respectively, and our net losses attributable to common stockholders were approximately \$26.6 million and \$2.6 million for the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019 and December 31, 2018, we had incurred cumulative net losses totaling approximately \$88.0 million and \$79.9 million, respectively. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may never generate sufficient product revenue (if any) to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant. We estimate that we will receive net proceeds of approximately \$3.3 million from the sale of securities offered by us in this offering.

We will need to raise more money to complete our planned clinical trials, continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. Notably, the proceeds raised in this offering will not be enough to complete our planned Phase 2 clinical trial of TSC for stroke or our Phase 3 clinical trial of TSC for treatment of glioblastoma multiforme. Additionally, we do not intend to commence our Phase 3 clinical trial of TSC for treatment of GBM prior to engaging in a strategic partnership. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. However, we may not be able to raise additional funds on acceptable terms, or at all. Conditions in the capital markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our research and development initiatives, reduce our workforce, license to others products or technologies that we otherwise would seek to commercialize ourselves or, ultimately, cease operations. The amount of money we may need would depend on many factors, including:

- The costs and progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

An investment in our securities is speculative and there can be no assurance of any return on any such investment.

An investment in our securities is speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in the Company, including the risk of losing their entire investment.

There will likely be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to fund research and development of our lead product candidate, TSC, including clinical trial activities. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

If we cannot continue to satisfy the Nasdaq Capital Market continued listing standards and other Nasdaq rules, our common stock could be delisted, which would harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. To maintain the listing of our common stock on the Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and stockholders' equity of at least \$2.5 million; or (ii) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and a total market value of listed securities of at least \$35 million.

As of November 12, 2019, our closing price per share of common stock was less than \$1.00 per share. There is no assurance that we regain compliance with the minimum closing price requirement and other listing requirements. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

The pre-funded warrants, Series I Warrants and Series II Warrants are speculative in nature.

None of the pre-funded warrants, Series I Warrants or Series II Warrants offered hereby confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the pre-funded warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of \$0.001 per share of common stock and holders of the Series I Warrants and Series II Warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of \$0.35 per share. There can be no assurance that it will ever be profitable for holders of the pre-funded warrants to exercise the pre-funded warrants or the holders of the Series I Warrants or Series II Warrants to exercise the Series I Warrants or Series II Warrants, respectively.

Holders of the pre-funded warrants, Series I Warrants and Series II Warrants will have no voting rights as common stockholders until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the pre-funded warrants, Series I Warrants and Series II Warrants, you will have no voting rights with respect to our common stock issuable upon exercise of the pre-funded warrants, Series I Warrants or Series II Warrants. Upon exercise of your pre-funded warrants, Series I Warrants or Series II Warrants, you will be entitled to exercise all the voting rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Significant holders or beneficial holders of our common stock may not be permitted to exercise pre-funded warrants, Series I Warrants or Series II Warrants that they hold.

The pre-funded warrants, Series I Warrants and Series II Warrants being offered hereby will prohibit a holder from exercising its pre-funded warrants, Series I Warrants or Series II Warrants if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 4.99% of our common stock outstanding immediately after giving effect to the exercise, provided that, at the election of a holder and notice to us, such beneficial ownership limitation shall be 9.99% of our common stock outstanding immediately after giving effect to the exercise. As a result, if you hold a significant amount of our securities, you may not be able to exercise your pre-funded warrants, Series I Warrants or Series II Warrants for shares of our common stock, in whole or in part, at a time when it would be financially beneficial for you to do so.

There is no public market for the pre-funded warrants, Series I Warrants or Series II Warrants to purchase shares of common stock being offered in this offering.

There is no established public trading market for the pre-funded warrants, Series I Warrants or Series II Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants, Series I Warrants or Series II Warrants on any national securities exchange or other trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants, Series I Warrants or Series II Warrants will be limited.

We may be limited in our ability to utilize, or may not be able to utilize, net operating loss carryforwards to reduce our future tax liability as a result of this offering.

As disclosed in our most recent Annual Report on Form 10-K, under Section 382 of Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss (“NOL”) carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited.

We believe that our reverse merger in January 2016 and other transactions that have occurred triggered an “ownership change” limitation that significantly limited our ability to utilize our NOL carryforwards. Our 2017, 2018 and 2019 financing transactions may have also triggered an ownership change, which could further limit our ability to utilize our NOL carryforwards. We have yet to determine this potential limitation. This offering may, alone or in conjunction with other changes in our stock ownership that we cannot control, result in an additional ownership change for purposes of Section 382. We may also experience ownership changes in the future as a result of strategic transactions or partnerships, equity offerings and other shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards and other deferred tax assets to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, similar limitations may apply at the state level and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

An investment in the pre-funded warrants, Series I Warrants, Series II Warrants and our common stock has numerous tax consequences.

There are numerous tax consequences to investors as a result of their investment in the Company. We encourage investors to seek advice from competent tax advisors as to the consequences of an investment in our pre-funded warrants, Series I Warrants, Series II Warrants and common stock (See “Material U.S. Federal Income Tax Considerations”).

The Bylaws of the Company include a forum selection clause, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Bylaws (the “Bylaws”) require that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein.

This exclusive forum provision will not apply to claims under the Exchange Act, but will apply to other state and federal law claims including actions arising under the Securities Act (although our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder). Section 22 of the Securities Act, however, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provisions. This forum selection provision in our Bylaws may limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents, which may discourage lawsuits against us and such persons. It is also possible that, notwithstanding the forum selection clause included in our Bylaws, a court could rule that such a provision is inapplicable or unenforceable.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the other information and documents incorporated by reference herein include forward-looking statements. We may, in some cases, use terms such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in and are incorporated by reference into a number of places throughout this prospectus and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our ability to commercialize our product candidates, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in or incorporated by reference into this prospectus, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in and incorporated by reference into this prospectus. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in and incorporated by reference into this prospectus, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our ability to obtain additional financing;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials;
- the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- 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;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- 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;
- our ability to satisfy the continued listing requirements of the Nasdaq Capital Market or any other exchange that our securities may trade on in the future;

- our ability to continue as a going concern;
- the success of competing products that are or may become available; and
- the performance of third parties, including contract research organizations and manufacturers.

You should also read carefully the factors described in the “Risk Factors” section contained in this prospectus and incorporated by reference herein from our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in or incorporated by reference into this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Any forward-looking statements that we make in or incorporate by reference into this prospectus speak only as of the date of such statement, and, except as required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$3.3 million from the sale of the securities offered by us in this offering after deducting the estimated Placement Agent's fees and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering to fund research and development of our lead product candidate, TSC, including clinical trial activities, and for general corporate purposes. See "Risk Factors" in this prospectus and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, incorporated by reference herein, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein, for a discussion of certain risks that may affect our intended use of the net proceeds from this offering, including that we will need to raise additional capital in the future to complete the development of TSC and our other product candidates.

We anticipate the estimated \$3.3 million of net proceeds, assuming no exercise of the warrants offered hereby, will be sufficient to fund our planned operations and research and development of TSC through at least the second quarter of 2020. Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for research and development of our lead product candidate, TSC, including clinical trial activities, and for general corporate purposes, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending the use of the net proceeds from this offering, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing securities or certificates of deposit.

CAPITALIZATION

The following table sets forth cash and capitalization as of September 30, 2019:

- on an actual basis;
- on an as adjusted basis to give effect to the issuance and sale of 5,104,429 Class A Units and 6,324,143 Class B Units in this offering (assuming the exercise of all of the pre-funded warrants included in the Class B Units, but excluding shares of common stock to be issued and any proceeds received upon exercise of the Series I Warrants or Series II Warrants), after deducting estimated Placement Agent's fees, and estimated offering expenses payable by us.

(unaudited)	<u>Actual as of September 30, 2019</u>	<u>As Adjusted as of September 30, 2019</u>
Cash and cash equivalents	\$ 6,139,770	\$ 9,444,770
Stockholders' equity:		
Common stock, par value \$0.001 per share; 1,000,000,000 shares authorized, 4,693,290 shares issued and outstanding actual; 1,000,000,000 shares authorized, 16,121,862 shares issued and outstanding as adjusted	4,694	16,122
Additional paid-in capital	\$ 101,486,119	\$ 104,779,691
Accumulated deficit	\$ (87,971,998)	\$ (87,971,998)
Total stockholders' equity	\$ 13,518,815	\$ 16,823,815
Total capitalization	\$ 13,518,815	\$ 16,823,815

The number of shares of our common stock to be outstanding after this offering is based on 4,693,290 shares of common stock outstanding as of September 30, 2019 and excludes as of that date:

- 309,276 shares of common stock issuable upon the exercise of outstanding stock options under the 2015 Equity Plan at a weighted-average exercise price of \$55.78 per share;
- 3,469,825 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of \$15.09 per share; and
- 19,740 shares of common stock reserved for future issuance under the 2015 Equity Plan.

DESCRIPTION OF CAPITAL STOCK

Company Capitalization

Our authorized capital stock consists of 1,000,000,000 shares of common stock and 30,000,000 shares of preferred stock, \$0.001 par value, all of which remains undesignated. The following summary is qualified in its entirety by reference to our Certificate of Incorporation, as amended, a copy of which is filed as an exhibit to our previous filings with the SEC and incorporated herein by reference.

Common Stock

Authorized. We are authorized to issue 1,000,000,000 shares of common stock, of which 4,693,290 shares were issued and outstanding as of September 30, 2019. We may amend from time to time our Certificate of Incorporation to increase the number of authorized shares of common stock. Any such amendment would require the approval of the holders of a majority of the voting power of the shares entitled to vote thereon.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in the holder's name on our books. Our common stock does not have cumulative voting rights. At all meetings of the stockholders, except where otherwise provided by law, the Certificate of Incorporation or Bylaws, the presence, in person or by proxy duly authorized, of the holders of a majority of the outstanding shares of common stock entitled to vote constitutes a quorum for the transaction of business. Except as otherwise provided by law or by the Certificate of Incorporation or Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of shares of common stock present in person or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by law, the Certificate of Incorporation or Bylaws, directors are elected by a plurality of the votes of the shares of common stock present in person or represented by proxy at the meeting and entitled to vote generally on the election of directors.

Dividends. Subject to limitations under Delaware law and any preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by our Board out of legally available funds.

Liquidation. Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of our company, subject to any prior rights of any preferred stock then outstanding.

Fully Paid and Non-assessable. All shares of our outstanding common stock are fully paid and non-assessable and any additional shares of common stock that we issue will be fully paid and non-assessable.

Other Rights and Restrictions. Holders of common stock do not have preemptive or subscription rights, and they have no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to common stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of preferred stock which we may designate in the future. Our Certificate of Incorporation and Bylaws do not restrict the ability of a holder of common stock to transfer the holder's shares of common stock.

Listing. Our common stock is quoted on the Nasdaq Capital Market under the symbol "DFFN." As of November 12, 2019, there were 515 record holders of our common stock.

Transfer Agent and Registrar. The transfer agent and registrar for common stock is Computershare Investor Services, LLC, 250 Royall Street, Canton, Massachusetts, telephone number: 1-800-942-5909.

Pre-Funded Warrants

The material terms and provisions of the pre-funded warrants being issued in this offering are summarized below. The following description is subject to, and qualified in its entirety by, the form of pre-funded warrant which is filed herewith as an exhibit. You should review the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants. See "Information Incorporated by Reference and Available Information" below.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Transferability. Subject to applicable laws, the pre-funded warrants are separately tradeable immediately after issuance at the option of the holders and may be transferred at the option of the holders upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

No Listing. There is no established public trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants on any securities exchange or trading system. Without an active market, the liquidity of the pre-funded warrants will be limited.

Fundamental Transactions. In the event of a "fundamental transaction," as defined in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Cashless Exercise. If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Rights as a Stockholder. Except as otherwise provided in the pre-funded warrant or by virtue of a holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Amendments. Amendments and waivers of the terms of the pre-funded warrants require the written consent of the holders of pre-funded warrants representing not less than a majority of the shares issuable upon exercise of the pre-funded warrants then outstanding and us, as well as any pre-funded warrant holder that would be disproportionately and materially adversely impacted by the amendment.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the pre-funded warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall or shall cause, at our option, the payment of a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the pre-funded warrant per whole share or round such fractional share up to the nearest whole share.

Series I Warrants

The material terms and provisions of the Series I Warrants being issued in this offering are summarized below. The following description is subject to, and qualified in its entirety by, the form of Series I Warrant which is filed herewith as an exhibit. You should review the form of Series I Warrant for a complete description of the terms and conditions applicable to the Series I Warrant. See “Information Incorporated by Reference and Available Information” below.

General. Each purchaser of Class A Units or Class B Units will receive a Series I Warrant to purchase one share of common stock for each unit purchased in the offering.

Exercisability. The Series I Warrants may be exercised at any time on or after their date of issuance, will have an exercise price of \$0.35 per share and are exercisable until the eighteen month anniversary of the date of issuance. The Series I Warrants will be exercisable, at the option of each holder, in whole or in part by delivering a duly executed exercise notice to us accompanied by payment in full for the number of shares of our common stock purchased upon such exercise. The exercise price of the Series I Warrant is subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Exercise Limitations. A holder of a Series I Warrant will not have the right to exercise any portion of the Series I Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at election of holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series I Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us provided that any increase shall not be effective until 61 days following notice to us.

Transferability. Subject to applicable laws, the Series I Warrants are separately tradeable immediately after issuance at the option of the holders and may be transferred at the option of the holders upon surrender of the Series I Warrant to us together with the appropriate instruments of transfer.

No Listing. There is no established public trading market for the Series I Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series I Warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series I Warrants will be limited.

Fundamental Transactions. In the event of a “fundamental transaction,” as defined in the warrant agreement and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series I Warrants will be entitled to receive upon exercise of the Series I Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series I Warrants immediately prior to such fundamental transaction.

Additionally, as more fully described in the Series I Warrants, in the event of certain fundamental transactions, the holders of the Series I Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Series I Warrants on the date of the consummation of such fundamental transaction.

Cashless Exercise. If, at the time a holder exercises its Series I Warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the Series I Warrant to the holder, and the holder is not able to sell the shares issuable upon exercise of the Series I Warrant without limitations on volume pursuant to Rule 144, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of our common stock determined according to a formula set forth in the Series I Warrant. In the event of a cashless exercise, if we fail to timely deliver the shares underlying the Series I Warrant, we will be subject to certain buy-in provisions.

Rights as a Stockholder. Except as otherwise provided in the Series I Warrant or by virtue of a holder’s ownership of shares of our common stock, the holders of the Series I Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series I Warrants.

Amendments. Amendments and waivers of the terms of the Series I Warrants require the written consent of the holders of Series I Warrants representing not less than a majority of the shares issuable upon exercise of the Series I Warrants then outstanding and us, as well as any Series I Warrant holder that would be disproportionately and materially adversely impacted by the amendment.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the Series I Warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall or shall cause, at our option, the payment of a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the Series I Warrant per whole share or round such fractional share up to the nearest whole share.

Series II Warrants

The material terms and provisions of the Series II Warrants being issued in this offering are summarized below. The following description is subject to, and qualified in its entirety by, the form of Series II Warrant which is filed herewith as an exhibit. You should review the form of Series II Warrant for a complete description of the terms and conditions applicable to the Series II Warrant. See “Information Incorporated by Reference and Available Information” below.

General. Each purchaser of Class A Units or Class B Units will receive a Series II Warrant to purchase one share of common stock for each unit purchased in the offering.

Exercisability. The Series II Warrants may be exercised at any time on or after their date of issuance, will have an exercise price of \$0.35 per share and are exercisable until the five year anniversary of the date of issuance. The Series II Warrants will be exercisable, at the option of each holder, in whole or in part by delivering a duly executed exercise notice to us accompanied by payment in full for the number of shares of our common stock purchased upon such exercise. The exercise price of the Series II Warrant is subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Exercise Limitations. A holder of a Series II Warrant will not have the right to exercise any portion of the Series II Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at election of holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series II Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us provided that any increase shall not be effective until 61 days following notice to us.

Transferability. Subject to applicable laws, the Series II Warrants are separately tradeable immediately after issuance at the option of the holders and may be transferred at the option of the holders upon surrender of the Series II Warrant to us together with the appropriate instruments of transfer.

No Listing. There is no established public trading market for the Series II Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series II Warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series II Warrants will be limited.

Fundamental Transactions. In the event of a “fundamental transaction,” as defined in the warrant agreement and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series II Warrants will be entitled to receive upon exercise of the Series II Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series II Warrants immediately prior to such fundamental transaction.

Additionally, as more fully described in the Series II Warrants, in the event of certain fundamental transactions, the holders of the Series II Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Series II Warrants on the date of the consummation of such fundamental transaction.

Cashless Exercise. If, at the time a holder exercises its Series II Warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the Series II Warrant to the holder, and the holder is not able to sell the shares issuable upon exercise of the Series II Warrant without limitations on volume pursuant to Rule 144, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of our common stock determined according to a formula set forth in the Series II Warrant. In the event of a cashless exercise, if we fail to timely deliver the shares underlying the Series II Warrant, we will be subject to certain buy-in provisions.

Rights as a Stockholder. Except as otherwise provided in the Series II Warrant or by virtue of a holder's ownership of shares of our common stock, the holders of the Series II Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series II Warrants.

Amendments. Amendments and waivers of the terms of the Series II Warrants require the written consent of the holders of Series II Warrants representing not less than a majority of the shares issuable upon exercise of the Series II Warrants then outstanding and us, as well as any Series II Warrant holder that would be disproportionately and materially adversely impacted by the amendment.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the Series II Warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall or shall cause, at our option, the payment of a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the Series II Warrant per whole share or round such fractional share up to the nearest whole share.

Undesignated Preferred Stock

As of September 30, 2019, no shares of preferred stock of the Company were issued or outstanding. Our Certificate of Incorporation authorizes our board of directors to provide for the issuance of up to 30,000,000 shares of preferred stock in one or more series and to fix the preferences, powers and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including the dividend rate, conversion rights, voting rights, redemption rights and liquidation preference, and to fix the number of shares to be included in any such series without any further vote or action by our stockholders. Any preferred stock so issued may rank senior to our common stock with respect to the payment of dividends or amounts upon liquidation, dissolution or winding up, or both. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any preferred stock.

Anti-Takeover Provisions

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers of the corporation and (b) shares issued under employee stock plans under which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by 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 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Warrants and Stock Options Issued and Outstanding

As of September 30, 2019, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share	Expiration dates
Common stock warrants issued prior to 2016	1,667	\$562.50	December 2019
Common stock warrants issued in 2017	903,870	\$33.30	March 2022
Common stock warrants issued in 2018	1,181,375	\$12.00 - \$15.00	January 2023
Common stock warrants issued in 2019	1,382,913	\$5.00 - \$6.11875	2024
	<u>3,469,825</u>		

Additionally, as of September 30, 2019, we had 309,276 shares of common stock issuable upon the exercise of outstanding stock options under the 2015 Equity Plan at a weighted-average exercise price of \$55.78 per share.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement dated October 7, 2019, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering, on a reasonable best efforts basis, of our Class A Units and our Class B Units pursuant to this prospectus. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The engagement agreement did not give rise to any commitment by the placement agent to purchase any of our units, and the placement agent had no authority to bind us by virtue of the engagement agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offer. The placement agent may engage sub-agents or selected dealers to assist with the offering.

We entered into a securities purchase agreement directly with institutional investors in connection with this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

We will deliver the securities underlying Class A Units and the Class B Units being issued to the investors upon receipt of investor funds for the purchase of the Class A Units and the Class B Units offered pursuant to this prospectus. We expect to deliver the shares of our common stock being offered pursuant to this prospectus on or about November 15, 2019.

Fees and Expenses

We have agreed to pay to the Placement Agent a cash fee equal to 8.0% of the aggregate gross proceeds raised in this offering. The following table shows the per Unit Placement Agent fees payable to the Placement Agent by us in connection with this offering.

	Per Class A Unit	Per Class B Unit
Public offering price	\$ 0.35	\$ 0.349
Placement Agent's fees payable by us	\$ 0.028	\$ 0.028
Proceeds, before expenses, to us	\$ 0.322	\$ 0.321

We estimate the total expenses payable by us for this offering to be approximately \$695,000, which amount includes (i) a placement agent's fee of \$320,000; (ii) a management fee equal to 1% of the aggregate gross proceeds raised in this offering; (iii) a \$25,000 non-accountable expense allowance payable to the Placement Agent; (iv) reimbursement of the accountable expenses of the Placement Agent equal to \$100,000 including the legal fees of the Placement Agent being paid by us (none of which has been paid in advance); (v) the Placement Agent's clearing expenses in the amount of \$10,000 in connection with this offering; and (vi) other estimated expenses of approximately \$200,000 which include legal, accounting, printing costs and various fees associated with the registration and listing of our shares. In addition, we have agreed to issue the Placement Agent's Warrants to the Placement Agent. See "Placement Agent's Warrants" below for additional detail.

Placement Agent's Warrants

We have agreed to issue to the Placement Warrants to purchase 571,429 shares of our common stock which represent 5% of the number of Class A Units and Class B Units being sold in this offering. The Placement Agent's Warrants will have a term of five years from the effective date of this prospectus and an exercise price per share equal to \$0.4375 per share, which represents 125% of the public offering price for the Class A Units sold in this offering. Pursuant to FINRA Rule 5110(g), the Placement Agent's Warrants and any shares issued upon exercise of the Placement Agent's Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Placement Agent or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Right of First Refusal

We have also agreed to give the Placement Agent a twelve-month right of first refusal to act as our sole underwriter or placement agent for any further capital raising transactions undertaken by us; and a twelve-month tail fee equal to the cash and warrant compensation in this offering if any investor with which we have had substantive discussions with respect to this offering provides us with further capital during such twelve-month period following termination of our engagement.

Lock-Up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, we may not offer for sale, contract to sell, or sell any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock subject to certain customary exception such as issuing stock options to directors, officers, employees and consultants under our existing plan and issuances of shares issuable upon the exercise of our outstanding warrants, including the warrants issued pursuant to this Prospectus. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Nasdaq Capital Market Listing

Our stock is currently traded on the Nasdaq Capital Market under the symbol "DFFN." On November 12, 2019, the last reported sale price of our common stock was \$0.55 per share. We do not plan to list the pre-funded warrants, Series I Warrants, Series II Warrants or the Placement Agent's Warrants on the Nasdaq Capital Market or any other securities exchange or trading market.

Indemnification

We have agreed to indemnify the Placement Agent and specified other persons against some civil liabilities, including liabilities under the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and to contribute to payments that the Placement Agent may be required to make in respect of such liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Other Relationships

The Placement Agent and its respective affiliates have in the past and may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The Placement Agent has received, or may in the future receive, customary fees and commissions for these transactions.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income considerations applicable to the ownership and disposition of shares of our common stock and warrants acquired in this offering. This discussion is for general information only and is not tax advice. Accordingly, all prospective holders of our common stock and warrants should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock and warrants. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences described in this prospectus. We assume in this discussion that each holder holds shares of our common stock and warrants as capital assets within the meaning of Section 1221 of the Code (generally property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular holder in light of that holder's individual circumstances, does not address the alternative minimum or Medicare contribution taxes, and does not address any aspects of U.S. state, local or non-U.S. taxes or any U.S. federal taxes other than income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address aspects of U.S. federal income taxation that may be applicable to investors that are subject to special tax rules, including without limitation:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- real estate investment trusts;
- pension plans, individual retirement accounts and other tax deferred accounts;
- persons that mark their securities to market;
- controlled foreign corporations;
- passive foreign investment companies;
- "dual resident" corporations;
- persons that receive our common stock or warrants as compensation for the performance of services;
- owners that hold our common stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- owners that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- persons that have a functional currency other than the U.S. dollar; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities for U.S. federal income tax purposes, or persons who hold our common stock or warrants through partnerships or other pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock or warrants should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock or warrants through a partnership or other pass-through entity, as applicable.

There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the U.S. federal income tax consequences of the purchase, ownership or disposition of our common stock or warrants.

Allocation of Purchase Price Between Common Stock or Pre-Funded Warrant and Accompanying Series I Warrant and Series II Warrant to Purchase Our Common Stock

The Class A Units will not be certificated and the shares of common stock, Series I Warrants and Series II Warrants comprising such unit are immediately separable and will be issued separately in this offering. The Class B Units will not be certificated and the pre-funded warrants, Series I Warrants and Series II Warrants comprising such unit are immediately separable and will be issued separately in this offering. Each holder of our common stock or pre-funded warrants and Series I Warrants and Series II Warrants must allocate the purchase price paid by such holder for our Class A Units and Class B Units among the share of common stock or pre-funded warrant, the Series I Warrant and the Series II Warrant based on the relative fair market value of each. This allocation will establish a holder's initial tax basis for U.S. federal income tax purposes in their shares of common stock or pre-funded warrants, Series I Warrants and Series II Warrants. We will not be providing holders with such allocation, and it is possible that different holders will reach different determinations regarding such allocation. A holder's allocation of purchase price between common stock or pre-funded warrants, Series I Warrants and Series II Warrants is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder's allocation.

Accordingly, each prospective holder should consult their own tax advisor with respect to the risks associated with an allocation of the purchase price between our common stock or pre-funded warrants, Series I Warrants and Series II Warrants.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the share of common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the share of common stock received upon exercise, increased by the exercise price of \$0.001 per share. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

U.S. Holders

This section applies to you if you are a "U.S. holder." For purposes of this discussion, a "U.S. holder" means a beneficial owner of our common stock and warrants who is for U.S. federal income tax purposes: (i) an individual who is a citizen or resident of the United States; (ii) a corporation, or any other organization taxable as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia; (iii) an estate, the income of which is subject to U.S. federal income tax regardless of its source; or (iv) a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock." Dividends paid by us will generally be eligible for the reduced rates of tax for qualified dividend income allowed to individual U.S. holders and for the dividends received deduction allowed to corporate U.S. holders, in each case assuming that certain holding period and other requirements are satisfied.

Conversion of Series I Warrants or Series II Warrants into Our Common Stock

Except as discussed below with respect to the cashless exercise of a Series I Warrant or Series II Warrant (together, the "common warrants"), a U.S. holder will not recognize gain or loss on the conversion of common warrants into our common stock. A U.S. holder's tax basis in the common stock received upon a conversion will equal the sum of (i) the initial tax basis of the common warrants converted and (ii) price paid upon exercise. The U.S. holder's holding period for the common stock received upon exercise of the common warrants will begin on the date following the date of exercise of the common warrants and will not include the period during which the U.S. holder held the common warrants.

The tax consequences of a cashless exercise of a common warrant are not clear under current U.S. tax law. A cashless exercise may be tax-free, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In this case, a U.S. holder's basis in the common stock received would equal the U.S. holder's basis in the common warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the common warrant.

It is possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized with respect to the common warrants surrendered to pay the exercise price for common warrants converted into common stock. In that event, a U.S. holder could be deemed to have surrendered only those common warrants used to satisfy the exercise price for an amount equal to the aggregate fair market value of the exercise price of the total number of common warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the amount deemed realized and the U.S. holder's tax basis in the common warrants surrendered to pay the exercise price. In this case, a U.S. holder's tax basis in the common stock received would equal the sum of the U.S. holder's initial investment in the converted common warrants (i.e., the portion of the U.S. holder's purchase price for the shares of common stock that is allocated to the common warrants, as described above under "—Allocation of Purchase Price between Common Stock and Warrants") and the exercise price of the common warrants converted. A U.S. holder's holding period for the common stock would commence on the date following the date of exercise.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their own tax advisors regarding the tax consequences of a cashless exercise.

If a common warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the common warrant.

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

Upon the sale, exchange, or other taxable disposition of our common stock or warrants, a U.S. holder will recognize gain or loss equal to the difference between the amount realized upon the disposition and the U.S. holder's tax basis in the common stock or warrants sold or exchanged. Any gain or loss generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder's holding period for the common stock or warrants exceeded one year at the time of the disposition. Certain U.S. holders (including individuals) are currently eligible for preferential rates of U.S. federal income taxation in respect of long-term capital gains. The deductibility of capital losses is subject to significant limitations.

Information Reporting and Backup Withholding

In general, information reporting requirements may apply to dividends paid to a U.S. holder on our common stock, and to the proceeds of the sale, exchange or other disposition of our common stock and warrants, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Non-U.S. Holders

This section applies to you if you are a "non-U.S. holder". For purposes of this discussion, a "non-U.S. holder" means a person who is not a U.S. holder (as defined above under "U.S. Holders").

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock."

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, or FATCA, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence, unless such dividends are effectively connected with a trade or business conducted by a non U.S. holder within the U.S (as discussed below). A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form), as applicable, and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may be able to obtain a refund or credit of any excess amounts withheld by timely filing the required information with the IRS.

Subject to the discussions below regarding backup withholding and FATCA, dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a "permanent establishment" or a "fixed base" maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. U.S. effectively connected income, net of specified deductions and credits, is generally taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Conversion of Common Warrants into Our Common Stock

The U.S. federal income tax treatment of a non-U.S. holder's exercise of a common warrant, or the lapse of a common warrant held by a Non-U.S. Holder, generally will correspond to the U.S. federal income tax treatment of the exercise or lapse of a common warrant by a U.S. Holder, as described under "U.S. Holders—Conversion of Common Warrants into Common Stock" above.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

Subject to the discussions below regarding backup withholding and FATCA, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other taxable disposition of shares of our common stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a "permanent establishment" or a "fixed base" maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on such gain at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Non-U.S. Holders—Distributions on Our Common Stock" also may apply to such gain;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the taxable disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the taxable disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or
- we are, or have been, at any time during the five-year period preceding such taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the taxable disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock or warrants, and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions paid on our common stock to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock or warrants. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Non-U.S. Holders—Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock and warrants by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS.

Withholding and Information Reporting Requirements—FATCA

FATCA may impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to certain foreign entities, unless (i) if the foreign entity is a “foreign financial institution,” such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a “foreign financial institution,” such foreign entity either certifies that it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign entity otherwise qualifies from an exemption these rules. Under applicable U.S. Treasury Regulations, withholding under FATCA currently applies to payments of dividends paid on our common stock. A Non-U.S. holder that is not subject to FATCA withholding generally may certify its exempt status by furnishing a properly executed IRS Form W-8BEN or Form W-8BEN-E (or successor form), as applicable. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. Certain intergovernmental agreements between the United States and other countries may modify these rules. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon for us by Dechert LLP. The placement agent is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of Diffusion Pharmaceuticals Inc. as of and for the years ended December 31, 2018 and 2017, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2018 consolidated financial statements contains an explanatory paragraph that states that the Company has suffered recurring losses from operations, has limited resources available to fund current research and development activities, and will require substantial additional financing to continue to fund its research and development activities that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the securities being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the securities offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

We file electronically with the SEC annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information and amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of these reports, proxy and information statements and other information may be obtained by electronic request at the following e-mail address: publicinfo@sec.gov.

We make available, free of charge and through our Internet web site at www.diffusionpharma.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also make available, free of charge and through our Internet web site, to any stockholder who requests, the charters of our board committees, our Corporate Governance Guidelines and our Code of Business Conduct and Ethics. Requests for copies can be directed to Investor Relations at (434) 220-0718. The information set forth on, or connected to, our website is expressly not incorporated by reference into, and does not constitute a part of, this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference information into this prospectus. This means we can disclose information to you by referring you to another document we filed with the SEC. We will make those documents available to you without charge upon your oral or written request. Requests for those documents should be directed to Investor Relations Department, Diffusion Pharmaceuticals Inc., 1317 Carlton Avenue, Suite 200, Charlottesville, Virginia 22902, Attention: Secretary, telephone: (434) 220-0718. This prospectus incorporates by reference the following documents (other than any portion of the respective filings furnished, rather than filed, under the applicable SEC rules) that we have filed with the SEC but have not included or delivered with this prospectus:

- our Annual Report on [Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 19, 2019](#);

- our Quarterly Reports on Form 10-Q for the fiscal quarters ended [March 31, 2019](#) , [June 30, 2019](#) and [September 30, 2019](#), filed with the SEC on May 9, 2019, August 8, 2019 and November 8, 2019, respectively;
- our Current Reports on Form 8-K filed with the SEC on [January 18, 2019](#), [May 28, 2019](#) and [June 13, 2019](#);
- our Definitive Proxy Statement on [Schedule 14A filed with the SEC on April 30, 2019](#); and
- the description of our common stock included in our amended registration statement on [Form 8-A filed on November 8, 2016](#) under the Exchange Act, and any amendment or report we may file with the SEC for the purpose of updating such description.

In addition, all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus (other than current reports or portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K).

You may request a free copy of any or all of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

Diffusion Pharmaceuticals Inc.
1317 Carlton Avenue, Suite 200
Charlottesville, Virginia 22902
(434) 220-0718
Attention: Investor Relations

In accordance with Rule 412 of the Securities Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

Diffusio₂n

Pharmaceuticals Inc.

**5,104,429 Class A Units consisting of Shares of Common Stock and Series I Warrants and Series II Warrants or
6,324,143 Class B Units consisting of Pre-Funded Warrants and Series I Warrants and Series II Warrants
11,428,572 Shares of Common Stock underlying the Series I Warrants
11,428,572 Shares of Common Stock underlying the Series II Warrants**

PROSPECTUS

H.C. Wainwright & Co.

November 13, 2019

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