

PROSPECTUS SUPPLEMENT
(To Prospectus dated July 9, 2021)

Processa Pharmaceuticals, Inc.

Up to \$15.0 Million and 123,609 Shares of Common Stock

This prospectus relates to the issuance and sale of up to \$15.0 million of shares of our common stock, or purchase shares, that we may sell to Lincoln Park Capital Fund, LLC (“Lincoln Park”), from time to time pursuant to the purchase agreement, dated March 23, 2022 (“Purchase Agreement”), that we have entered into with Lincoln Park, and an additional 123,609 shares of our common stock issued to Lincoln Park as commitment shares under the Purchase Agreement. This prospectus also covers the resale of these shares by Lincoln Park to the public. See “Lincoln Park Transaction” for a description of the Purchase Agreement and additional information regarding Lincoln Park. Lincoln Park is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended, or the Securities Act.

The purchase price for the purchase shares will be based upon formulas set forth in the Purchase Agreement depending on the type of purchase notice we submit to Lincoln Park from time to time. We will pay the expenses incurred in registering the shares of our common stock, including legal and accounting fees. See “Plan of Distribution.”

Our common stock is listed on the Nasdaq Capital Market under the trading symbol “PCSA.” On March 23, 2022, the last reported sale price of our common stock on the Nasdaq Capital Market was \$3.25 per share.

Investing in our common stock involves risks. See “Risk Factors” beginning on page S-8 of this prospectus supplement and in our Annual Report on Form 10-K for the year ended December 31, 2020 and our other periodic reports filed with the Securities and Exchange Commission (the “SEC”), and incorporated by reference herein.

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

The date of this prospectus supplement is March 23, 2022.

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For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See the sections titled “Where You Can Find More Information” in the accompanying prospectus “Incorporation of Certain Documents by Reference” in this prospectus supplement.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement, the accompanying prospectus or any applicable free writing prospectus in making a decision about whether to invest in our common stock. We have not, and Lincoln Park has not, authorized any other person to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, any securities in any jurisdiction where it is unlawful to make such an offer or solicitation. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, any applicable free writing prospectus and the documents incorporated by reference herein or therein is accurate only as of their respective dates or on the date or dates which are specified in these documents. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of our common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of our common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus to or by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus dated July 9, 2021, gives more general information, some of which may not apply to this offering.

To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or documents incorporated by reference, the information in this prospectus supplement will supersede such information.

This prospectus supplement does not contain all of the information that is important to you. You should read the accompanying prospectus as well as the documents incorporated by reference in this prospectus supplement and the accompanying prospectus. See “Incorporation of Certain Documents by Reference” in this prospectus supplement and “Where You Can Find More Information” in the accompanying prospectus.

Processa’s name and logo are either registered trademarks or trademarks of Processa Pharmaceuticals, Inc. in the United States and/or other countries and jurisdictions. All other trademarks, service marks or other tradenames appearing in this prospectus supplement and the accompanying prospectus are the property of their respective owners.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement to the “Company,” “Processa,” “we,” “us,” “our” or similar references mean Processa Pharmaceuticals, Inc., a Delaware corporation, and its wholly owned subsidiary.

FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein contain certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act, and Section 21E of the Exchange Act. All statements other than statements of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain funding for our future operations;
- the impact of the ongoing COVID-19 pandemic on our business, operations or ability to obtain funding;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for our product candidates, if approved;

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- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our product candidates, if approved;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates by physicians, patients, third-party payors and others in the medical community, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

Forward-looking statements reflect our management’s expectations or predictions of future conditions, events or results based on various assumptions and management’s estimates of trends and economic factors in the markets in which we are active, as well as our business plans. They are not guarantees of future performance. By their nature, forward-looking statements are subject to risks and uncertainties. Our actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. There are a number of factors that could cause actual conditions, events or results to differ materially from those described in the forward-looking statements contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein.

See an additional discussion under “Risk Factors” in any applicable prospectus supplement and any related free writing prospectus, and in our most recent Annual Report on Form 10-K and any subsequently filed quarterly reports on Form 10-Q. These forward-looking statements are representative only as of the date they are made, and we

PROSPECTUS SUPPLEMENT SUMMARY

Overview

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions for which few or no treatment options currently exist. We are a clinical-stage development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options. In order to increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties that has been shown to be effective in the population.

Our screening criteria for identifying and selecting new candidates include:

- addressing an unmet or underserved clinical need,
- having demonstrated evidence of efficacy in humans, and
- leveraging our regulatory science approach to improve the probability for approval.

In many instances, these clinical candidates have significant pre-clinical and clinical data that we may leverage to high value inflection points while de-risking the programs and adding in optionality to potential future indications. Our regulatory science approach developed by our team over decades of work with regulatory authorities attempts to balance the “benefit/risk” equation to identify a regulatory path with higher clinical benefit and/or lower risk with shorter timelines to deliver better treatment options to patients, physicians and caregivers.

Our pipeline includes drugs that (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication; (ii) target indications for which a single positive pivotal study demonstrating efficacy might provide enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug or the present standard of care (e.g., some orphan indications, many serious life-threatening conditions, some serious quality of life conditions); and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired time-frame to demonstrate that the drug can, at some level, treat or potentially treat patients with the condition.

To advance our mission, we have assembled an experienced and successful development team with a track record of drug approvals and successful exits. Our team is experienced in developing drug products through all principal regulatory tiers from IND enabling studies to NDA submission. The combined scientific, development and regulatory experience of our team members has resulted in more than 30 drug approvals by the FDA, over 100 meetings with the FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need. Although we believe that the skills and experience of our team members in drug development and commercialization is an important indicator of our future success, the past successes of our team members in developing and commercializing pharmaceutical products does not guarantee that they will successfully develop and commercialize drugs in our current pipeline. In addition, the growth in revenues of companies at which our executive officers and directors served in was due to many factors and does not guarantee that they will successfully operate or manage us or that we will experience similar growth in revenues, even if they continue to serve as executive officers and/or directors.

Our ability to generate meaningful revenue from any products depends on our ability to out-license the drugs before or after we obtain FDA NDA approval. Even if our products are authorized and approved by the FDA, it should be noted that the products must still meet the challenges of successful marketing, distribution and consumer acceptance.

Our Strategy

Our strategy is to obtain and develop drugs that will not only treat patients with unmet medical need conditions but, with our Regulatory Science approach, also have the potential to be more efficiently developed with a greater probability of development success than what typically occurs in the biotech-pharma industry and a better return on investment given lower development costs, more efficient development and high commercial value. Given the prior successes of our Regulatory Science approach, we have selected drugs for our portfolio which may have greater chance for approval in a population of patients who desperately need better treatment options. We have applied rigorous standards to identify drugs for our portfolio, namely:

- The drug must represent a treatment option to patients with a high unmet medical need condition by improving survival and/or quality of life for these patients;
- The drug or its metabolite or a drug with similar pharmacological properties must have demonstrated some evidence of efficacy in the target population, and;
- The drug presents opportunities to be developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization and adding to the potential for a high return on investment.

Our Team

Our drug development efforts are guided by our knowledge and experience in applying rigorous regulatory science to decrease manageable risks, costs and time toward achieving marketing authorization from regulatory authorities including the FDA. We have assembled a seasoned management team and development team with extensive experience in developing therapies, including advancing product candidates from preclinical research through clinical development and ultimately regulatory approval and commercialization. Our team is led by our Chairman and CEO David Young, Pharm.D., Ph.D. who has extensive experience in research, regulatory approval and business development and who served at Questcor for eight years, initially as an independent director and subsequently as its Chief Scientific Officer. Dr. Young’s guidance led to the approval of Acthar in Infantile Spasms and the ultimate sale of Questcor in 2014.

Our Drug Pipeline

We currently have five drugs: four in various stages of clinical development (PCS499, PCS12852, PCS3117, and PCS6422) and one in nonclinical development (PCS11T). We group our drugs into non-oncology (PCS499 and PCS12852) and oncology (PCS3117, PCS6422 and PCS11T). A summary of each drug is provided below:

- Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (NL) in late 2020, and in May 2021 we enrolled the first patient in our Phase 2B trial for the treatment of ulcerative NL. We expect to complete our interim analysis and complete enrollment of the Phase 2B trial by the end of 2022; and, depending on the results, begin a pivotal Phase 3 trial in 2023.

- PCS12852 is a highly specific and potent 5HT4 agonist which has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, complete enrollment in the second half of 2022, and complete final analysis in the first half of 2023.
- PCS3117, which we licensed in June 2021, is a cytosine analog, similar to gemcitabine (Gemzar®) but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. We are evaluating biomarkers to elucidate specifically which patients are more likely to benefit from PCS3117 compared to gemcitabine and other chemotherapy agents to provide a more targeted, precision medicine approach to the treatment of various types of cancer, such as pancreatic and/or non-small cell lung cancer. Over the next 6-12 months, we will be developing, refining and qualifying these biomarker assays for use in our clinical trials as well as define the potential paths to approval for different types of cancer. We anticipate initiating a Phase 2B or adaptive designed Phase 3 in 2023.

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- PCS6422 is an orally administered irreversible enzyme inhibitor administered in combination with capecitabine. When combining capecitabine with PCS6422 (the “Next Generation Capecitabine”), capecitabine becomes a more potent cancer chemotherapy agent than current FDA approved capecitabine. On August 2, 2021, we enrolled the first patient in our Phase 1B dose-escalation maximum tolerated dose trial in patients with advanced refractory gastrointestinal (GI) tract tumors and our interim analysis of Cohorts 1 and 2 found no dose-limiting toxicities (DLTs), no drug related adverse events greater than Grade 1, and no hand-foot syndrome. In addition, the interim analysis revealed when PCS6422 inhibits DPD enzyme activity, 5-FU metabolism is significantly decreased (< 10% metabolized to F-Bal compared to typically 80%) and the potency of capecitabine is significantly increased (at least 50 times greater 5-FU potency based on systemic exposure per mg of capecitabine administered). The single dose of PCS6422, however, did not sustain the DPD inhibition throughout 7 days of capecitabine dosing which was needed to maintain the improved potency of capecitabine. Therefore, we have modified the existing protocol to obtain more data on DPD inhibition and de novo formation. We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition for each patient treated with this Next Generation Capecitabine (i.e., combination of PCS6422 and capecitabine). After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the second quarter of 2022 and complete enrollment while defining the Next Generation Capecitabine regimen (i.e., the PCS6422 regimens and the corresponding capecitabine regimens) by the end of 2022. We expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.
- Our only non-clinical asset is PCS11T, an analog of SN38 (SN38 being the active metabolite of irinotecan), and a next generation irinotecan drug for multiple types of cancers. PCS11T is presently in the IND pre-clinical toxicology stage. We hope to submit an IND in 2023, followed by a Phase 1B maximum tolerated dose trial.

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Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Planned Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		Interim Analysis and Complete Trial Enrollment by the end of 2022
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders			*		FPI Phase 2A Complete Enrollment by the end of 2022
PCS3117 Phase 2B	Pancreatic, Non- Small Cell Lung Cancer			*		Develop Biomarker Assays 1H'22; Initiate Phase 2B Study 2023
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer		*			Restart Phase 1B 2Q'22; Complete Enrollment 2022
PCS11T Pre-IND	Small Cell Lung; Colorectal Cancer					Initiate IND Enabling Studies

* Cleared by FDA for Clinical Trial

Our Annual Report on Form 10-K for the year ended December 31, 2020 and subsequently filed Quarterly Reports on Form 10-Q provide additional information about our business, operations and financial condition.

Corporate Information

We were incorporated under the laws of the State of Delaware on March 29, 2011. Our principal executive office is located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076. Our telephone number is (443) 776-3133.

We make available free of charge on or through our Internet website (<http://www.processapharmaceuticals.com>) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). The SEC also maintains a website which provides on-line access to reports and other information regarding registrants that file electronically with the SEC at: www.sec.gov.

The information contained on our website and social media channels is not included as a part of, or incorporated by reference into, this prospectus.

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THE OFFERING

Common stock offered by us: 123,609 shares of our common stock issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, or the commitment shares, and up to \$15.0 million of shares of our common stock, or the purchase shares, that we may sell to Lincoln Park from time to time prior to March 23, 2025, at our sole discretion, in accordance with the Purchase Agreement. We will not receive any cash proceeds from the issuance of the commitment shares.

Common Stock offering: 20,459,006 shares, assuming sale of 4,615,385 shares at a price of \$3.25 per share, which was the closing price of our common stock on Nasdaq on March 23, 2022, together with the 123,609 shares of our common stock issued to Lincoln Park as commitment shares, and without regard to the 19.99% Exchange Cap described in the “Lincoln Park Transaction” section of this prospectus. The actual number of shares issued will vary depending on the sales prices in this offering, but, when taken together with the 123,609 shares sold or issued to Lincoln Park under the Purchase Agreement prior to the date of this prospectus, will not be greater than 3,142,430 shares representing 19.99% of the shares of our common stock outstanding on the date of the Purchase Agreement, unless in accordance with Nasdaq Market rules.

Use of proceeds:	We intend to use the net proceeds that we receive from any sales to Lincoln Park under the Purchase Agreement for general corporate purposes, which may include conducting clinical trials, research and development activities and working capital, as well as for capital expenditures, investment and acquisitions or licensing transactions. See “Use of Proceeds” on page S-10.
Risk factors:	An investment in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement and other information included in this prospectus supplement, the accompanying prospectus and the documents incorporated by references in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol:	“PCSA”

The number of shares of our common stock to be outstanding immediately after this offering is based on 15,599,062 shares of common stock outstanding as of September 30, 2021, and excludes:

- 145,357 shares of common stock issuable upon the exercise of vested stock options at a weighted average exercise price of \$7.50 per share;
- 100,731 shares of common stock issuable for vested restricted stock units (RSUs) issuable upon meeting distribution restrictions;
- 254,930 shares of common stock issuable upon the future vesting of RSUs;
- 303,725 shares of common stock issuable upon exercise of warrants (of which 266,225 are vested) at a weighted-average exercise price of \$10.66 per share; and
- 1,899,696 shares of common stock reserved for future awards under our equity incentive plans.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Prior to making a decision about investing in our common stock, you should consider carefully the specific risk factors discussed in the sections entitled “Risk Factors” contained in our most recent Annual Report on Form 10-K for the year ended December 31, 2020, and subsequent Quarterly Reports on Form 10-Q which are incorporated into this prospectus supplement and the accompanying prospectus by reference in their entirety, as updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement and the accompanying prospectus, together with other information in this prospectus supplement and the accompanying prospectus, the documents incorporated by reference and any free writing prospectus that we may authorize for use in connection with this offering. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us, or that we currently view as immaterial, may also impair our business. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be unduly relied upon to anticipate results or trends in future periods. If any of the risks or uncertainties described in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and cash flow could be materially and adversely affected. In that case, the trading price of our common stock could decline and you might lose all or part of your investment. Please also read carefully the section above titled “Forward-Looking Statements.”

Risks Relating to this Offering

Our management will have broad discretion to use the net proceeds from this offering, and our investment of these proceeds pending any such use may not yield a favorable return.

Our management will have broad discretion as to the use of the net proceeds from this offering by us and could use them for purposes other than those contemplated at the time of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for us.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of our common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 23, 2022, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$15.0 million of our common stock, subject to certain limitations contained in the Purchase Agreement. We are issuing 123,609 shares of common stock, or commitment shares, to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time until March 23, 2025. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. The exercise of outstanding stock options and warrants or the settlement of restricted stock units may result in further dilution of your investment. See “Dilution” in this prospectus for a more detailed illustration of the dilution you would incur if you participate in this offering.

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You may experience future dilution as a result of future issuances of common stock, including through equity offerings or acquisition.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering. The prices per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

Future issuances of common stock could further depress the market for our common stock. We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may include sales of significant amounts of common stock to strategic investors, and which common stock may be subject to registration rights. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets or in private transactions may adversely affect the market price of our common stock and our stock price may decline substantially. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

If we make one or more significant acquisitions in which the consideration includes common stock or other securities, our stockholders' holdings may be significantly diluted. In addition, stockholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock, which could impair your ability to sell any shares of common stock that you purchase in this offering at prices above the price you pay in this offering and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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USE OF PROCEEDS

We may receive up to \$15.0 million in aggregate gross proceeds from sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. We estimate that the net proceeds to us from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will be up to \$14.95 million over the remaining period of the Purchase Agreement (ending on March 23, 2025), assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under the Purchase Agreement, and after other estimated fees and expenses. We may sell fewer than all of the shares offered by this prospectus, in which case our net offering proceeds will be less. Because we are not obligated to sell any additional shares of our common stock under the Purchase Agreement the actual total offering amount and proceeds to us are not determinable at this time. There can be no assurance that we will receive any additional proceeds under or fully utilize the Purchase Agreement. See "Plan of Distribution" elsewhere in this prospectus for more information.

We intend to use the net proceeds that we receive from sales to Lincoln Park under the Purchase Agreement for general corporate purposes, which may include conducting clinical trials, research and development activities and working capital, as well as for capital expenditures, investment and acquisitions or licensing transactions.

Our management will have broad discretion to allocate the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus supplement for any purpose. Pending application of the net proceeds as described above, we may initially invest the net proceeds in short-term, investment-grade, interest-bearing securities or apply them to the reduction of short-term liabilities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

As of September 30, 2021, we had net tangible book value of approximately \$17.6 million, or \$1.22 per share, based on an aggregate of 15,599,062 shares of our common stock outstanding as of that date. Historical net tangible book value per share represents the amount of total tangible assets, less total liabilities, divided by the outstanding number of shares of our common stock. Dilution in net tangible book value per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards.

Without taking into account any other changes in net tangible book value after September 30, 2021, after giving effect to the assumed sale by us of 4,615,385 shares of our common stock under this prospectus (which excludes the 123,609 commitment shares issued to Lincoln Park) at an assumed sale price of \$3.25 per share of our common stock, which was the last reported sale price of our common stock on Nasdaq on March 23, 2022, and without giving effect to the 19.99% issuance cap under the Purchase Agreement, and after deducting estimated aggregate offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2021 would have been approximately \$33,990,421, or \$1.67 per share of common stock. This represents an immediate increase in net tangible book value per share of \$0.45 to our existing stockholders.

Assumed public offering price per share		\$	3.25
Historical net tangible book value per share as of September 30, 2021	1.22		
Increase in net tangible book value per share attributable to new investors	<u>0.45</u>		
As adjusted net tangible book value per share after this offering			<u>1.67</u>
Dilution per share to new investors purchasing shares in this offering		\$	<u>1.58</u>

The number of shares of our common stock to be outstanding immediately after this offering is based on 15,599,062 shares of common stock outstanding as of September 30, 2021, and excludes:

- 145,357 shares of common stock issuable upon the exercise of vested stock options at a weighted average exercise price of \$7.50 per share;
- 100,731 shares of common stock issuable for vested restricted stock units (RSUs) issuable upon meeting distribution restrictions;
- 254,930 shares of common stock issuable upon the future vesting of RSUs;

- 303,725 shares of common stock issuable upon exercise of warrants (of which 266,225 are vested) at a weighted-average exercise price of \$10.66 per share; and
- 1,899,696 shares of common stock reserved for future awards under our equity incentive plans.

To the extent that any of these outstanding options are exercised at prices per share below the public offering price per share in this offering or we issue additional shares under our equity incentive plans at prices below the public offering price per share in this offering, there will be further dilution to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any options or warrants are exercised, new options are issued under our equity incentive plans, or we otherwise raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to new investors.

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LINCOLN PARK TRANSACTION

General

On March 23, 2022, we entered into the Purchase Agreement with Lincoln Park. In connection with the Purchase Agreement, on March 23, 2022 we also entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we agreed to take specific actions to maintain the registration of the shares of our common stock subject to the offering described in this prospectus. Pursuant to the terms of the Purchase Agreement and the Registration Rights Agreement, Lincoln Park has agreed to purchase from us up to \$15.0 million of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we have filed with the SEC this prospectus regarding the sale under the Securities Act of the shares issuable to Lincoln Park under the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we are issuing 123,609 commitment shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

We may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock subject to the satisfaction of certain conditions set forth in the Purchase Agreement at a purchase price per share based on the market price of our common stock at the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of the Nasdaq Capital Market, we may not issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of 3,142,430 shares (including the commitment shares), which represents 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement, or the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of our common stock in excess of the Exchange Cap, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$3.38 per share (which represents the lower of (A) the official closing price of our common stock on Nasdaq on the date of the Purchase Agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the date of the Purchase Agreement, adjusted such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules). In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of the Nasdaq Capital Market.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park, would result in Lincoln Park and its affiliates exceeding 9.99% of the outstanding shares of our common stock (the “Beneficial Ownership Limitation”).

Purchase of Shares under the Purchase Agreement

Regular Purchases

Under the Purchase Agreement, on any business day selected by us, if the closing sale price of our common stock on Nasdaq is not below \$1.00, we may direct Lincoln Park to purchase up to 25,000 shares of our common stock on such business day (or the purchase date), which we refer to as a Regular Purchase, provided, however, that (i) a Regular Purchase may be increased to up to 50,000 shares if the closing sale price of our common stock on Nasdaq is not below \$6.00 on the applicable purchase date and (ii) a Regular Purchase may be increased to up to 75,000 shares, if the closing sale price of our common stock on Nasdaq is not below \$8.00 on the applicable purchase date. Lincoln Park’s committed under each Regular Purchase cannot exceed \$1,250,000. In each case, upon the parties’ mutual agreement, the maximum amount of any single Regular Purchase may be increased. We may direct Lincoln Park to purchase shares in Regular Purchases as often as every business day. The foregoing share amounts and per share prices will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring after the date of this prospectus.

The purchase price per share for each such Regular Purchase will be equal to the lesser of:

- the lowest sale price for our common stock on Nasdaq on the purchase date of such shares; or
- the average of the three lowest closing sale prices for our common stock on Nasdaq during the 10 consecutive business days prior to the purchase date of such shares.

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Accelerated Purchases

We may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice for the maximum amount allowed for such Regular Purchase to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, of up to the lesser of:

- 300% of the number of shares to be purchased pursuant to such Regular Purchase; and
- 30% of the aggregate shares of our common stock traded on Nasdaq during the period on the trading day immediately following the purchase date for such Regular Purchase, which we refer to as the “Accelerated Purchase Date,” beginning at the commencement of regular trading on Nasdaq (or such later time on such Accelerated Purchase Date as mutually agreed by us and Lincoln Park specified in the Accelerated Purchase notice for such Accelerated Purchase), and ending at the close of regular trading on Nasdaq on such Accelerated Purchase Date, or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed prior to the close of regular trading on Nasdaq on the applicable Accelerated Purchase Date, ending at such earlier time that any one of such thresholds is crossed, which period of time on the applicable Accelerated Purchase Date we refer to as the “Accelerated Purchase Measurement Period.”

The purchase price per share for each such Accelerated Purchase will be equal to 95% of the lesser of:

- the closing sale price on the applicable Accelerated Purchase Date; and

- the volume-weighted average price of our common stock on Nasdaq during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date.

The parties may mutually agree to increase the number of shares to be purchased by Lincoln Park pursuant to any Accelerated Purchase.

Additional Accelerated Purchases

We also have the right to direct Lincoln Park, prior to 1:00 p.m., Eastern time, on an Accelerated Purchase Date for an Accelerated Purchase for which the applicable Accelerated Purchase Measurement Period has theretofore ended and all of the shares subject thereto have been properly delivered to Lincoln Park, to purchase additional shares of our common stock in another Accelerated Purchase, which we refer to as an Additional Accelerated Purchase, on the same business day, which in reference to an Additional Accelerated Purchase we refer to as an Additional Accelerated Purchase Date, of up to the lesser of:

- 300% of the number of shares purchased pursuant to the applicable corresponding Regular Purchase; and
- 30% of the aggregate shares of our common stock traded on Nasdaq during the period on the applicable Additional Accelerated Purchase Date beginning at the time mutually agreed by us and Lincoln Park and specified in the Additional Accelerated Purchase notice for such Additional Accelerated Purchase, and ending at the close of regular trading on Nasdaq on such Additional Accelerated Purchase Date, or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed prior to the close of regular trading on Nasdaq on such date, ending at such earlier time that any one of such thresholds is crossed, which period of time on the applicable Additional Accelerated Purchase Date we refer to as the "Additional Accelerated Purchase Measurement Period".

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We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park on a single Additional Accelerated Purchase Date, provided that (i) such Additional Accelerated Purchase notice is received by Lincoln Park prior to 1:00 p.m., Eastern time, on such Additional Accelerated Purchase Date and (ii) all prior Accelerated Purchases and Additional Accelerated Purchases (including those that have occurred earlier on the same trading day) have been completed and all of the shares to be purchased thereunder have theretofore been properly delivered to Lincoln Park in accordance with the Purchase Agreement.

The purchase price per share for each such Additional Accelerated Purchase will be equal to 95% of the lower of:

- the volume-weighted average price of our common stock on Nasdaq during the applicable Additional Accelerated Purchase Measurement Period on the applicable Additional Accelerated Purchase date; and
- the closing sale price of our common stock on Nasdaq on the applicable Additional Accelerated Purchase date.

We and Lincoln Park may mutually agree to increase the number of shares to be purchased by Lincoln Park pursuant to any Additional Accelerated Purchase.

In the case of Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus supplement and accompanying prospectus form a part lapses for any reason (including, without limitation, the issuance of a stop order by the SEC), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- suspension by the principal market of our common stock from trading or failure of the common stock to be listed on the Nasdaq for a period of one business day;
- the de-listing of our common stock from the Nasdaq Capital Market, our principal market, unless our common stock is immediately thereafter trading on the Nasdaq Global Select Market, the Nasdaq Global Market, the New York Stock Exchange, the NYSE American, the NYSE Arca, the OTC Bulletin Board or the OTC Markets (or any other comparable market) a nationally recognized successor to any of the foregoing;
- the failure for any reason by our transfer agent to issue purchase shares to Lincoln Park within two business days after any purchase date, Accelerated Purchase date or Additional Accelerated Purchase date, as applicable, on which Lincoln Park is entitled to receive such purchase shares;
- any breach of the representations, warranties, covenants or other terms or conditions contained in the Purchase Agreement or Registration Rights Agreement that has or could have a Material Adverse Effect (as defined in the Purchase Agreement) and, in the case of a breach of a covenant that is reasonably curable, that is not cured within a period of at least five business days;
- our common stock ceases to be DTC authorized and ceases to participate in the DWAC/FAST systems;

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- if at any time the Exchange Cap (to the extent applicable under the terms of the Purchase Agreement) is reached and our stockholders have not approved the issuance of common stock in excess of the Exchange Cap in accordance with the applicable rules of the Nasdaq Capital Market; or
- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above, however, the Purchase Agreement will automatically terminate upon initiation of insolvency or bankruptcy proceedings by or against us. During an event of default, all of which are outside of Lincoln Park's control, we are not permitted to direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give one (1) business day prior written notice to Lincoln Park to terminate the Purchase Agreement.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

Prohibitions on Variable Rate Transactions

Subject to specified exceptions included in the Purchase Agreement, we are limited in our ability to enter into specified variable rate transactions during the term of the Purchase Agreement. Such transactions include, among others, the issuance of convertible securities with a conversion or exercise price that is based upon or varies with the trading price of our common stock after the date of issuance, the issuance of securities with embedded anti-dilution provisions, the issuance of securities with an embedded put or call right or at a price subject to being reset after the initial issuance contingent on our business or market performance or entry into any new “equity line of credit.”

Effect of Performance of the Purchase Agreement on our Stockholders

All shares registered in this offering that have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. Shares registered in this offering may be sold over a period commencing on the date of this prospectus and ending on March 23, 2025. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

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Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$15.0 million of our common stock (exclusive of the 123,609 commitment shares we are issuing to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement). The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement (i) shares of our common stock in excess of the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$3.38 per share, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules and (ii) any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park, would exceed the Beneficial Ownership Limitation.

The table below sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices.

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase(1)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park(2)	Gross Proceeds from the Sale of Shares to Lincoln Park Under the \$15 Million Purchase Agreement
\$ 3.00	3,142,430	17.20 %	9,427,291
\$ 3.25(3)	3,142,430	17.20 %	10,212,899
\$ 5.00	3,000,000	16.58 %	15,000,000
\$ 6.00	2,500,000	14.30 %	15,000,000
\$ 8.00	1,875,000	11.28 %	15,000,000

(1) Includes the total number of purchase shares that we would have sold under the Purchase Agreement at the corresponding assumed average purchase price set forth in the first column, up to the aggregate purchase price of \$15,000,000, if available, while giving effect to the Exchange Cap and without regard for the Beneficial Ownership Limitation, and excludes the commitment shares.

(2) The denominator is based on 15,843,621 shares outstanding as of March 23, 2022 including the issuance of 123,609 commitment shares issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement and adjusted for the number of shares set forth in the adjacent column that we would have sold to Lincoln Park, assuming the average purchase price in the first column. The numerator is based on the number of shares issuable under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed average purchase price set forth in the first column.

(3) The closing sale price of our common stock on Nasdaq on March 23, 2022.

PLAN OF DISTRIBUTION

Pursuant to this prospectus, we are offering up to \$15.0 million in shares of our common stock and 123,609 shares of our common stock to Lincoln Park as commitment shares pursuant to the Purchase Agreement. This prospectus also covers the resale of these shares by Lincoln Park to the public.

We may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 25,000 shares on any single business day from and after the Commencement, which amounts may be increased to up to 75,000 shares of our common stock depending on the market price of our common stock at the time of sale. The foregoing share amounts and related market prices will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring after the date of this prospectus. In addition, upon notice to Lincoln Park, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase additional shares of our common stock in “accelerated purchases,” and/or “additional accelerated purchases” as set forth in the Purchase Agreement. The purchase price per share is based on the market price of our common stock at the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. See “Lincoln Park Transaction-Purchases of Shares under the Purchase Agreement.”

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Lincoln Park is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act.

We will pay \$25,000 to Lincoln Park as Lincoln Park’s full and complete expense reimbursement in connection with entering into the transaction, including any due

diligence expenses and legal fees. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of our common stock offered.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes Lincoln Park, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus supplement.

This offering will terminate on the date that all shares offered by this prospectus supplement have been sold to Lincoln Park.

Our common stock is listed on The Nasdaq Stock Market LLC and trades under the symbol "PCSA." The transfer agent of our common stock is Equiniti Trust Company.

LEGAL MATTERS

The validity of the common stock offered by this prospectus supplement will be passed upon for us by Foley & Lardner LLP, Jacksonville, Florida. Lincoln Park is being represented by Dorsey & Whitney LLP, New York, New York.

EXPERTS

The consolidated financial statements incorporated in this prospectus supplement by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2020 have been audited by BD & Company, Inc., an independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information that is incorporated by reference is considered to be part of this prospectus supplement, and the information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference any future filings we make with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the termination of this offering and the following documents (other than information in documents that is deemed not to be filed, including the portions of these documents that are furnished under items 2.02 or Item 7.01 of a Current Report on Form 8-K, including any exhibits included with such Items):

- our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021 and amended on April 7, 2021;
- our Proxy Statement on Schedule 14A for the 2021 Annual Meeting of Stockholders, filed April 22, 2021;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2021, June 30, 2021 and September 30, 2021
- our Current Reports on Form 8-K filed with the SEC on February 18, 2021, May 26, 2021, June 10, 2021, June 17, 2021, August 20, 2021, November 5, 2021 and January 6, 2022; and
- the description of our common stock contained in or incorporated into our Registration Statement on Form 8-A, filed September 17, 2020, and any amendment or report updating that description.

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PROSPECTUS



Processa Pharmaceuticals

Common Stock
Preferred Stock
Warrants
Units

We may offer and sell from time to time up to \$75,000,000 of any combination of the securities described in this prospectus, in one or more classes or series and in amounts, at prices and on terms that we will determine at the times of the offerings.

This prospectus describes the general manner in which our securities may be offered using this prospectus. We will provide specific terms of the securities, including the offering prices, in one or more supplements to this prospectus. The supplements may also add, update or change information contained in this prospectus. You should read this prospectus and the prospectus supplement relating to the specific issue of securities carefully before you invest. This prospectus may be used to offer and sell any of the securities for the account of persons other than us as provided in an applicable prospectus supplement.

We may offer the securities independently or together in any combination for sale directly to purchasers or through underwriters, dealers or agents to be designated at a future date. The supplements to this prospectus will provide the specific terms of the plan of distribution.

Our common stock is traded on the Nasdaq Capital Market under the symbol "PCSA." On June 25, 2021, the closing price of our common stock on the Nasdaq

Capital Market was \$8.62 per share.

Investment in our securities involves a high degree of risk. Before making an investment decision, please read the information in the section titled “Risk Factors” on page 5 of this prospectus. Please read carefully and consider these risk factors, as well as those included in reports we file under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), such as our most recent Annual Report on Form 10-K, and those included in any applicable prospectus supplement and/or other offering material we file with the Securities and Exchange Commission (the “SEC”).

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 9, 2021.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the SEC using a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$75,000,000. This prospectus sets forth certain terms of the securities that we may offer.

This prospectus provides a general description of the securities we may offer. Each time we offer securities, we will, to the extent required by law, provide a prospectus supplement to this prospectus. The prospectus supplement will contain the specific description of the securities we are then offering and the terms of the offering. The prospectus supplement will supersede this prospectus to the extent it contains information that is different from, or that conflicts with, the information contained in this prospectus. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. You should read this prospectus, any prospectus supplement and any other offering material together with the documents incorporated herein by reference and the additional information described herein under the heading “Where You Can Find More Information” before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus and any accompanying prospectus supplement. We have not authorized anyone else to provide you with different or additional information. We are offering to sell these securities and seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate.

You should not assume that the information contained in this prospectus and any accompanying supplement to this prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying supplement to this prospectus is delivered or securities are sold on a later date.

This prospectus may not be used by us to consummate sales of our securities unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

As used in this prospectus, unless the context indicates or otherwise requires, “the Company,” “our Company,” “we,” “us,” and “our” refer to Processa Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiary.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act, and Section 21E of the Exchange Act. All statements other than statements of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain funding for our future operations;
- the impact of the COVID-19 pandemic on our business, operations or ability to obtain funding;

- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for our product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our product candidates, if approved;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates by physicians, patients, third-party payors and others in the medical community, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

Forward-looking statements reflect our management's expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. They are not guarantees of future performance. By their nature, forward-looking statements are subject to risks and uncertainties. Our actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. There are a number of factors that could cause actual conditions, events or results to differ materially from those described in the forward-looking statements contained in this prospectus and the documents incorporated by reference into this prospectus.

See an additional discussion under "Risk Factors" in any applicable prospectus supplement and any related free writing prospectus, and in our most recent Annual Report on Form 10-K and any subsequently filed quarterly reports on Form 10-Q. These forward-looking statements are representative only as of the date they are made, and we undertake no obligation to update any forward-looking statement as a result of new information, future events or otherwise.

PROSPECTUS SUMMARY

Overview

We are a clinical-stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for patients who have a high unmet medical need condition that affects survival or the patient's quality of life and have few or no treatment options.

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions. We are a development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options than presently exist for their medical condition. In order to increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties has been shown to be effective in the population.




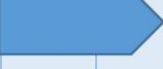

Our screening criteria for identifying and selecting new candidates include:

- addressing an unmet or underserved clinical need,
- having demonstrated evidence of efficacy in humans and
- leveraging our regulatory science approach to improve the probability for approval.

We currently have four drugs in various stages of clinical development and one drug in nonclinical development. Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We have completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (NL) and in May 2021 enrolled our first patient in our Phase 2B trial for the treatment of ulcerative NL. PCS6422, our second drug, is an orally administered irreversible enzyme inhibitor administered in combination with capecitabine. We anticipate enrolling the first patient in July 2021 in our Phase 1B dose-escalation study in patients with Advanced Refractory Gastrointestinal (GI) Tract Tumors.

PCS12852 is a very specific and very potent 5HT4 agonist which has already been evaluated in clinical studies in South Korea for gastric emptying and GI motility. We are planning on submitting an IND application in the third quarter of 2021 for the treatment of gastroparesis based on our pre-IND communications with the FDA and plan to begin enrolling patients in the first quarter of 2022. Our fourth clinical asset, PCS3117, was recently acquired and is a cytosine analog, similar to gemcitabine (Gemzar®) but different enough that some patients are more likely to respond to PCS3117 than gemcitabine. Potential biomarkers to predict which patients are more likely to respond to PCS3117 will be developed and evaluated over the next 9-12 months in order to provide a more targeted, precision medicine approach to treating pancreatic cancer and/or non-small cell lung cancer. Further validation of this approach will be assessed in a Phase 2B study expected to start in the second half of 2022 followed by a Phase 3 registration trial. Our only non-clinical asset is PCS11T, an analog of SN38 (SN38 being the active metabolite of irinotecan). PCS11T is presently in the IND pre-clinical toxicology stage. We hope to submit an IND in late 2022 or first half of 2023.

Our clinical pipeline (shown below) summarizes each drug, organized by the stage of development. We have enrolled our first patient in our PCS499 Phase 2B study and expect to enroll our first patient in our PCS6422 Phase 1B PCS6422 study in July 2021.

Program	Indications	Pre-Clinical	Phase I	Phase II	Phase III	Key Upcoming Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica					Interim analysis in the first half 2021; release final clinical data in the second half of 2022; conduct Phase 3 study in the first half of 2023
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer					Complete biomarker assay in the third quarter of 2022; enroll first patient in a Phase 2B study in the second half of 2022; conduct Phase 3 study in the second half of 2023
PCS12852 Phase 2A	Gastroparesis, GI Motility Disorders					Obtain FDA clearance for Phase 2A study in the fourth quarter of 2021; enroll first patient in the first quarter of 2022; interim analysis in third quarter of 2022; release final clinical data in 2023
PCS6422 Phase 2B	Colorectal (colon, metastatic), Metastatic Breast Cancer					Enroll first patient in a Phase 1B study in the first half of 2021; interim cohort analyses to start second half of 2021; conduct dose escalation study in the third quarter of 2022; conduct Phase 2B-3 study in the second half of 2023
PCS11T IND Enabling	Small Cell Lung, Pancreatic Cancer					Submit Phase 1B IND between late 2022 or early 2023

Our Annual Report on Form 10-K for the year ended December 31, 2020 and subsequently filed Quarterly Reports on Form 10-Q provide additional information about our business, operations and financial condition.

Corporate Information

We are a Delaware corporation and our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076. Our telephone number is (443) 776-3133. Our website is www.processapharmaceuticals.com. The information found on, or otherwise accessible through, our website is not incorporated into, and does not form a part of, this prospectus or any other report or document we file with or furnish to the SEC. We have included our website address in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the specific risks set forth under the caption “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequently filed quarterly reports on Form 10-Q, incorporated into this prospectus by reference, as updated by any future filings we make under the Exchange Act. You should consider carefully those risk factors together with all of the other information included and incorporated by reference in this prospectus before investing in any shares of common stock offered by this prospectus. For more information, see “Where You Can Find More Information.” These risks are not the only ones faced by us. Additional risks not known, or that are deemed immaterial could also materially and adversely affect our financial condition, results of operations, our drug candidates, business and prospects. Any of these risks might cause you to lose all or part of your investment.

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USE OF PROCEEDS

Unless we indicate otherwise in the applicable prospectus supplement, the net proceeds from the sale of the securities will be used for general corporate purposes, which may include conducting clinical trials, research and development activities, working capital, capital expenditures, investments and acquisitions or licensing transactions.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus for any purpose. Pending application of the net proceeds as described above, we may initially invest the net proceeds in short-term, investment-grade, interest-bearing securities or apply them to the reduction of short-term liabilities.

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DESCRIPTION OF SECURITIES

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws. Reference is made to the more detailed provisions of, and the descriptions are qualified in their entirety by reference to, the Certificate of Incorporation and Bylaws, forms of which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part, and applicable law.

General

We, directly or through one or more underwriters, dealers and agents designated from time to time, or directly to purchasers, or through a combination of these methods, may offer, issue and sell, together or separately, in one or more offerings, the following securities:

- shares of our common stock;
- shares of our preferred stock, in one or more series;

- warrants to purchase shares of our common stock or preferred stock;
- units consisting of any combination of the securities listed above, each on terms to be determined at the time of sale.

The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock, or other securities. The common stock, preferred stock, warrants, and units are collectively referred to in this prospectus as the “securities.” When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

We have the authority to issue an aggregate of 30,000,000 shares of \$0.0001 par value common stock and 1,000,000 shares of \$0.0001 par value preferred stock. As of June 25, 2021, there were 15,566,305 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Dividend Rights. Subject to the rights of holders of preferred stock of any series that may be issued and outstanding from time to time, holders of our common stock are entitled to receive such dividends and other distributions as may be declared by our Board of Directors from time to time.

Voting Rights. Each outstanding share of our common stock is entitled to one vote on all matters submitted to a vote of stockholders generally. In the event we issue one or more series of preferred or other securities in the future such preferred stock or other securities may be given rights to vote, either together with the common stock or as a separate class on one or more types of matters. The holders of our common stock do not have cumulative voting rights.

Liquidation Rights. In the event of any liquidation, dissolution or winding up of the Company, the holders of our common stock will be entitled, subject to any preferential or other rights of any then outstanding preferred stock, to receive all assets of the Company available for distribution to stockholders.

Preemptive Rights. As of the date hereof, the holders of our common stock have no preemptive rights in their capacities as such holders.

Board of Directors. Holders of common stock do not have cumulative voting rights with respect to the election of directors. At any meeting to elect directors by holders of our common stock, the presence, in person or by proxy, of the holders of a majority of the voting power of shares of our capital stock then outstanding will constitute a quorum for such election. Directors may be elected by a plurality of the votes of the shares present and entitled to vote on the election of directors, except for directors whom the holders of any then outstanding preferred stock have the right to elect, if any.

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Preferred Stock

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 1,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock. As of the date of this prospectus, there were no shares of preferred stock outstanding.

Restricted Stock

During the year ended December 31, 2020, we granted 336,860 restricted stock awards to our employees and directors. On August 5, 2020, we issued 324,360 restricted stock awards under the 2019 Omnibus Incentive Plan to our employees and directors, of which 214,078 shares of common stock vested on October 6, 2020 when we successfully completed our underwritten public offering and up-listed to the Nasdaq Capital Market. The remaining 110,282 shares of common stock vest on the first and second year anniversaries of the grant date. Certain employees forfeited 23,804 shares to pay for federal, state and local income taxes, leaving 319,306 restricted stock awards outstanding. In the fourth quarter of 2020, we issued 12,500 restricted stock awards to our Chief Operating Officer upon hire which vest one year from their hiring date. We valued the restricted stock awards based on the closing shares price on the date of grant.

At March 31, 2021, we had 122,782 shares of unvested restricted stock that was granted in 2020 outstanding. During the three months ended March 31, 2021, we issued 12,500 restricted stock units (RSUs) and 100,000 warrants to a consultant for services to be provided in 2021. We valued the RSUs based on the closing share price on the date of grant. The fair value of the warrants granted was estimated using the Black-Scholes option pricing model at the date of grant. During the three months ended March 31, 2021, we also agreed to grant 64,556 RSUs to our employees and a consultant in accordance with our employment/consulting agreements.

Stock Options

In 2019, we granted stock options for the purchase of 129,919 shares of our common stock to employees and directors. The stock options awarded contained either service or performance vesting conditions, have a contractual term of five years and an exercise price of \$16.80. At March 31, 2021, we had outstanding options to purchase 152,806 shares of our common stock of which options for the purchase of 115,750 shares of our common stock were vested. All the options outstanding have exercise prices higher than the closing market price at March 31, 2021.

During the three months ended March 31, 2021, we granted 30,000 stock options to a consultant in accordance with a consulting agreement.

Warrants

We may issue warrants, in one or more series, for the purchase of our common stock or preferred stock. Warrants may be issued independently or together with our common stock or preferred stock and may be attached to or separate from any offered securities.

A prospectus supplement accompanying this prospectus relating to a particular series of warrants will describe the terms of those warrants, including:

- the title and the aggregate number of warrants,
- the security for which each warrant is exercisable,
- the date or dates on which the right to exercise such warrants commence and expire,

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- the price or prices at which such warrants are exercisable,
- the periods during which and places at which such warrants are exercisable,

- the terms of any mandatory or optional call provisions,
- the price or prices, if any, at which the warrants may be redeemed at the option of the holder or will be redeemed upon expiration,
- the identity of the warrant agent, and
- the exchanges, if any, on which such warrants may be listed.

You should read the particular terms of the documents pursuant to which the warrants will be issued, which will be described in more detail in the applicable prospectus supplement.

As of the date of this prospectus, we have outstanding warrants to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 530,268 shares of common stock, including:

- 276,543 shares of common stock issuable upon the exercise of outstanding warrants allowing the holders to purchase shares of common stock. The exercise price for 275,828 shares is \$19.07 per share and for 715 shares is \$17.16. These warrants expire between June 29, 2021 and July 29, 2021. Warrants for 18,819 shares of common stock contain cashless exercise provisions.
- 18,107 shares of common stock issuable upon the exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of \$17.16 per share expiring on July 2, 2022.
- 56,350 shares of common stock issuable upon the exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of \$19.04 per share through December 19, 2023.
- 100,000 shares of common stock issuable upon the exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of \$7.18 per share through January 11, 2023.
- 79,268 shares of common stock upon exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of \$9.30 per share through February 16, 2023.

Units

We may issue units consisting of one or more warrants, shares of preferred stock, shares of common stock or any combination of such securities. The applicable prospectus supplement will describe the terms of the units and of the securities comprising the units, including whether and under what circumstances the securities comprising the units may be traded separately. You should read the particular terms of the documents pursuant to which the units will be issued, which will be described in more detail in the applicable prospectus supplement.

Indemnification of Directors and Officers

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by the Delaware General Corporate Law (“DGCL”) as it may hereafter be amended, none of our directors will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Under the DGCL as it now reads, such limitation of liability is not permitted:

- for any breach of the director’s duty of loyalty to us or our stockholders;

- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for payments of unlawful dividends or unlawful stock purchases or redemptions under Section 174 of the DGCL; or
- for any transaction from which the director derived an improper personal benefit.

These provisions will have no effect on the availability of equitable remedies such as an injunction or rescission based on a director’s breach of his or her duty of care.

Our amended and restated certificate of incorporation and our amended and restated bylaws include provisions that require us to indemnify and advance expenses, to the fullest extent allowable under the DGCL as it now exists or may hereafter be amended, to our directors or officers for actions taken as a director or officer of us, or for serving at our request as a director or officer at another corporation or enterprise, as the case may be.

Section 145 of the DGCL provides that a corporation may indemnify directors and officers, as well as other employees and individuals, against expenses, including attorneys’ fees, judgments, fines and amounts paid in settlement, that are incurred in connection with various actions, suits or proceedings, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, known as a derivative action, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, if they had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses, including attorneys’ fees, incurred in connection with the defense or settlement of such actions, and the statute requires court approval before there can be any indemnification if the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation’s bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our amended and restated bylaws require us to indemnify any person who was or is a party or is threatened to be made a party to, or was otherwise involved in, a legal proceeding by reason of the fact that he or she is or was a director or officer of the Company or is or was serving at our request as a director or officer of another corporation or enterprise, as the case may be, to the fullest extent authorized by the DGCL as it now exists or may hereafter be amended, against all expense, liability and loss (including attorneys’ fees, judgments, fines, Employee Retirement Income Security Act excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such director or officer in connection with such service. The right to indemnification in our amended and restated bylaws includes the right to be paid by the Company the expenses incurred in defending any proceeding for which indemnification may be sought in advance of the final disposition of such proceeding, subject to certain limitations. We carry directors’ and officers’ insurance protecting us, any director, officer, employee or agent of ours or who was serving at the request of the Company as a director, officer, employee or agent of another corporation or enterprise, as the case may be, against any expense, liability or loss, whether or not we would have the power to indemnify the person under the DGCL.

The limitation of liability and indemnification and advancement provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of fiduciary duty. These provisions also may reduce the likelihood of derivative litigation against our directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment in our common stock may be adversely affected to the extent we pay the costs of settlement and damage awards under these indemnification provisions.

Certain Anti-Takeover Effects

Provisions of Delaware Law. We are a Delaware corporation and Section 203 of the DGCL applies to us. It is an anti-takeover statute that is designed to protect stockholders against coercive, unfair or inadequate tender offers and other abusive tactics and to encourage any person contemplating a business combination with us to negotiate with our Board of Directors for the fair and equitable treatment of all stockholders.

Under Section 203 of the DGCL, a Delaware corporation is not permitted to engage in a “business combination” with an “interested stockholder” for a period of three years following the date that the stockholder became an interested stockholder. As defined for this purpose, the term “business combination” includes a merger, consolidation, asset sale or other transaction resulting in a financial benefit to the interested stockholder. The term “interested stockholder” is defined to mean a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation’s outstanding voting stock. This prohibition does not apply if:

- prior to the time that the stockholder became an interested stockholder, the Board of Directors of the corporation approved either the business combination or the transaction resulting in the stockholder becoming an interested stockholder;
- upon completion of the transaction resulting in the stockholder becoming an interested stockholder, the stockholder owns at least 85% of the outstanding voting stock of the corporation, excluding voting stock owned by directors who are also officers and by certain employee stock plans; or
- at or subsequent to the time that the stockholder became an interested stockholder, 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 two-thirds of the outstanding voting stock that the interested stockholder does not own.

A Delaware corporation may elect not to be governed by these restrictions. We have not opted out of Section 203.

Advance Notice Procedures. Our bylaws establish an advance notice procedure for stockholder nominations of persons for election to our Board of Directors and for any proposals to be presented by stockholders at an annual meeting. Stockholders at an annual meeting will only be able to consider nominations and other proposals specified in the notice of meeting or brought before the meeting by or at the direction of our Board of Directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our corporate secretary timely written notice, in proper form, of the stockholder’s intention to nominate a person for election as a director or to bring a proposal for action at the meeting.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “PCSA.”

Transfer Agent and Registrar

Our transfer agent is Equiniti Trust Company, 3200 Cherry Creek Dr. South Suite 430 Denver, CO 80209; telephone (303) 282-4800.

PLAN OF DISTRIBUTION

We may sell the securities on a delayed or continuous basis through one or more agents, underwriters or dealers, directly to one or more purchasers, through a combination of any of these methods of sale, in negotiated transactions (including block trades), in transactions that are deemed to be “at the market” offerings as defined in Rule 415 of the Securities Act or in any other manner, as provided in the applicable prospectus supplement. We will identify the specific plan of distribution, including any underwriters, dealers, agents or direct purchasers and their compensation in a prospectus supplement.

We may distribute the securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to prevailing market prices; or
- at negotiated prices.

In connection with the sale of the securities, underwriters may be deemed to have received compensation from us in the form of underwriting discounts or commissions and may also receive commissions from purchasers of the securities for whom they may act as agent. Underwriters may sell the securities to or through dealers, and dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agent.

If we use an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale and we will provide the name of any underwriter in the applicable prospectus supplement. We will describe in the applicable prospectus supplement any underwriting compensation we pay to underwriters or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements with any underwriters, dealers and agents which may entitle them to indemnification against and contribution toward certain civil liabilities, including liabilities under the Securities Act, and to reimbursement for certain expenses.

Unless we specify otherwise in the related prospectus supplement, each series of securities offered will be a new issue with no established trading market. We may elect to list any series of securities on any exchange, but we are not obligated to do so. It is possible that one or more underwriters or agents may make a market in a series of offered securities, but will not be obligated to do so and may discontinue any market making at any time without notice. Therefore, we cannot assure you as to the liquidity of the trading market for the securities.

If indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or other persons acting as our agents to solicit offers by certain institutions or other suitable persons to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in the prospectus supplement. We may make delayed delivery with various institutions, including commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions. Delayed delivery contracts will be subject to the condition that the purchase of the securities covered by the delayed delivery contracts will not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject. The underwriters and agents will not have any responsibility with respect to the validity or performance of these contracts.

To facilitate an offering of a series of the securities, certain persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities

than we sold to them. In these circumstances, these persons would cover the over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Foley & Lardner LLP.

EXPERTS

The consolidated financial statements of the Company as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019 appearing in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, have been audited by BD & Company, Inc., an independent registered public accounting firm, as set forth in their report thereon and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We also filed a registration statement on Form S-3, including exhibits, under the Securities Act with respect to the securities offered by this prospectus. This prospectus is a part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. The SEC maintains a web site, www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may review the registration statement and any other document we file on the SEC's web site. Our SEC filings are also available to the public on our website, www.processapharmaceuticals.com. The information on our website, however, is not, and should not be deemed to be, a part of this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We are "incorporating by reference" specified documents that we file with the SEC, which means:

- incorporated documents are considered part of this prospectus;
- we are disclosing important information to you by referring you to those documents; and
- information we file with the SEC will automatically update and supersede information contained in this prospectus.

We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date we filed the registration statement of which this prospectus is a part and before the effective date of the registration statement and any future filings we will make with the SEC under those sections, except to the extent that any information in such filing is deemed "furnished" in accordance with rules of the SEC:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 25, 2021 and amended on April 7, 2021;
- Our Proxy Statement on Schedule 14A for the 2021 Annual Meeting of Stockholders, filed with the SEC on April 22, 2021;
- Our Quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 13, 2021;
- Our Current Reports on Form 8-K filed with the SEC on February 18, 2021 (excluding Item 7.01 and the exhibit related thereto), May 26, 2021, June 10, 2021 and June 17, 2021; and
- the description of our common stock contained in or incorporated into our Registration Statement on Form 8-A, filed September 17, 2020, and any amendment or report updating that description.

Notwithstanding the foregoing, documents or portions thereof containing information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits under Item 9.01, are not incorporated by reference in this prospectus.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of any of these filings, at no cost, by request directed to us at the following address or telephone number:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, Maryland 21076
(443) 776-3133
Attention: Wendy Guy

You should not assume that the information in this prospectus or any prospectus supplement, as well as the information we file or previously filed with the SEC that we incorporate by reference in this prospectus or any prospectus supplement, is accurate as of any date other than the respective date of such documents. Our business, financial condition, results of operations and prospects may have changed since that date.



Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS, INC.

Up to \$15.0 Million and 123,609 Shares of Common Stock

PROSPECTUS SUPPLEMENT

The date of this prospectus supplement is March 23, 2022
