UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): June 17, 2025

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware45-1539785(State or Other Jurisdiction of
Incorporation or Organization)(I.R.S. Employer
Identification Number)

601 21st Street, Suite 300, Vero Beach, FL 32960

(Address of Principal Executive Offices, Including Zip Code)

(772) 453-2899

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock: Par value \$.0001	PCSA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

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

Item 1.01. Entry into a Material Agreement.

On June 17, 2025, Processa Pharmaceuticals, Inc. (the "Company") entered into a Binding Term Sheet (the "Term Sheet") with Intact Therapeutics. ("Intact"), granting Intact the exclusive option to license PCS12852, a highly specific and potent 5HT4 agonist that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients.

Upon execution of the Term Sheet, the Company received a non-refundable standstill payment of \$20,000 and upon execution of a license agreement, the Company will receive a 3.5% equity interest in Intact and a payment of \$2.5 million, with \$1.0 million paid within thirty days of closing and the remaining \$1.5 million paid within twelve months of closing. The Term Sheet also provides that the license agreement will provide for development and regulatory milestone payments, commercial milestone payments based on net product sales and a 12% royalty on worldwide net sales of licensed products, excluding South Korea.

The obligations of the parties to enter into the license agreement are subject to additional diligence by Intact, the negotiation and execution of a license agreement and other conditions including an amendment of the Company's license agreement with Yuhan Corporation. Pursuant to the Term Sheet, the parties have one hundred and twenty (120) days to finish any remaining due diligence and enter into the license agreement, which period may be extended for an additional one hundred and twenty days for an additional fee of \$30,000. There can be no assurance that the Company and Intact will enter into a definitive license agreement or that Yuhan Corporation will agree to amend the license agreement with the Company.

In connection with the entry into the Term Sheet, the Company plans to enter into Amendment No. 1 to the License Agreement dated August 19, 2020 with Yuhan Corporation (the "Amendment"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

Pursuant to the Amendment, the licensor will extend the time frame during which the Company is required to dose a first patient with a product in a Phase 2B clinical trial. In addition, the Amendment will increase the sublicense payment percentage to 60% for sublicenses prior to a Phase 2B clinical trial, 50% after a Phase 2B clinical trial and 40% after a Phase 3 clinical trial.

The above summary of the Binding Term Sheet above is not complete and is subject to the full terms and conditions of the agreement, which is attached hereto as Exhibit 10.1, and incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On June 17, 2025, the Company issued a press release announcing the entry into a Binding Sublicense Agreement. The press release is attached hereto as Exhibit 99.1 and incorporated by reference in this Item 7.01.

The information contained in Item 7.01 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
10.1	Binding Term Sheet by and between Processa Pharmaceuticals and Intact Therapeutics
99.1	Press Release dated June 17, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on June 17, 2025.

PROCESSA PHARMACEUTICALS, INC. Registrant

By: /s/ George Ng

George Ng Chief Executive Officer

BINDING TERM SHEET FOR OPTION AND LICENSE ("TERM SHEET")

A. Transaction; Subject to the terms of the Yuhan License Agreement (as License; defined herein), Processa Pharmaceuticals, Inc. ("Processa") Payments; shall grant Intact Therapeutics ("Intact") an option right during the Standstill Period (as defined herein) to an exclusive, royalty **Royalties:** bearing license in the Territory (as defined herein) in the Field (as defined herein), with the right to sublicense, to practice the Technology (as defined herein) to research, develop, make, have made, use, sell and import products including the Technology ("Products") in the Field of Use (as defined herein) ("License"), and Processa shall grant such License upon the Closing, at which time Processa has obtained payment of the Standstill Payment, the Standstill Extension Payment (if applicable), the Option Exercise Payment, and Intact is in good standing with respect to such payments that fall due at or prior to the Closing; and Processa shall receive the payments set forth below and herein; and Processa and Yuhan Corporation ("Yuhan"), an intended third party beneficiary, shall each be granted ownership interests in Intact in the percentages set forth below (the "Transaction").

Equity Stake:

Upon the Closing, Intact shall grant an irrevocable ownership interest totaling 7% of the issued equity distributed to Processa. and to Yuhan, as follows:

Processa: 3.5% Yuhan: 3.5%

In addition to the granted ownership interests set above, the following payments shall be made to Processa:

<u>Standstill Payment</u>: Intact shall pay Processa a non-refundable fee of \$20,000 ("*Standstill Payment*') upon execution of this Term Sheet ("*Term Sheet Execution Date*").

<u>Option Exercise Payments</u>: Intact shall pay Processa a minimum non-refundable fee of \$1,000,000 within thirty (30) days of the Closing, and \$1,500,000, within twelve months of the Closing, ("*Option Exercise Payment*").

<u>Milestone Payments</u>: Intact shall pay Processa the milestone payments set forth in Appendix A ("*Milestone Payments*").

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<u>Royalties</u>: Intact shall pay Processa a twelve percent (12%) royalty rate on worldwide accrued annual net sales in the Territory of products developed or derived from the Technology, including, but, not limited to PCS 12852 (as defined herein), such royalty obligations will expire on the later of the last patent expiry date for any patent or pending patent application in respect of the Technology, or the commercial market launch of a generic product with substantial equivalence to any product derived from the Technology.

The Parties agree that they will structure the payments herein in a tax efficient manner for Processa and that any such structure will be subject to the mutual agreement of the Parties.

B. Standstill; The Parties shall have one hundred twenty (120) days after the Term Sheet Execution Date to finish any remaining due Closing **Conditions:** diligence and to enter into the License Agreement ("Standstill Period"). During the Standstill Period, Processa may not initiate or engage in any licensing or partnering transaction discussions with any third parties that relate to PCS 12852 (as defined herein) ("Standstill Restrictions"). For the sake of clarity, the Standstill Restrictions do not apply to any discussions regarding mergers, company acquisitions and financings and other non-licensing or partnering transactions that do not solely relate to PCS 12852 (as defined herein) or relate to any back-up compounds or other compounds (as defined in Technology). For the sake of additional clarity, the Standstill Restrictions also do not apply to licensing or partnering discussions with any third parties relating solely to other drug products and technologies not related to PCS 12852, such as, but not limited to, PCS 499, PCS 6422, PCS 3117 and PCS 11T.

During the Standstill Period, Intact shall have the following obligations:

- 1. Confirm a target indication for PCS 12852; and
- 2. Develop a draft clinical study protocol for PCS 12852 (as defined herein) ("*Intact Standstill Obligations*").

Upon mutual agreement by the Parties and Intact paying \$30,000 to Processa ("*Standstill Extension Payment*"), the Standstill Period may be extended for another one hundred twenty (120) days ("*Standstill Extension*"); provided that Intact is not in material breach of this Term Sheet.

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If the Parties do not execute the License Agreement and Intact does not complete the Intact Standstill Obligations to Processa's reasonable satisfaction or otherwise violates the terms of this Term Sheet within the Standstill Period or Standstill Extension, this Term Sheet terminates, the Standstill Restrictions cease to apply and any and all rights granted in this Term Sheet and any License Agreement (as defined herein) automatically revert back to Processa.

The obligations of the Parties to complete the Transaction contemplated ("Closing"), on the "*Closing Date*" meaning the final day of the Standstill Period or earlier, herein will be subject, among other things, to the satisfaction of all of the following conditions (each a "*Closing Condition*" and, collectively "*Closing Conditions*"):

(i) negotiation, execution and delivery of the License Agreement (as defined herein);

(ii) receipt of all necessary governmental, board of directors, existing shareholder and third-party approvals;

(iii) representations and warranties are true and accurate as of the Closing Date; and

(iv) the Standstill Payment, and any other outstanding payments owed to Processa by Intact have been paid to and actually received by Processa.

The "Technology" means the Patent Rights, other intellectual property, Regulatory Filings, and other discoveries, data, know-how and technical information, data and technical information owned or controlled by Processa that are directly and specifically related to: 1) PCS 12852; or 2) any back-up compounds or other compounds that may be licensed to Processa by Yuhan in the License Agreement By And Between Processa Pharmaceuticals, Inc. and Yuhan Corporation dated August 19, 2020 ("Yuhan License Agreement"), subject to terms of the Yuhan License Agreement or necessary for Intact to effectuate the intent of the License. "Patent Rights" means all patents and patent applications owned or controlled by Processa that are related to or are otherwise reasonably necessary for Intact to exploit the Technology in accordance with the license agreement into which it enters. "Regulatory Filings" means all regulatory filings owned or controlled by

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C. Technology; Territory; Field of Use:

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Processa that relate to Technology, including any regulatory filing that Processa has a right to reference (including through a third-party) that relate to Technology. For the sake of clarity, Technology, Patent Rights and/or Regulatory Filings do not pertain to or include any of Processa's other technologies, drug product candidates, and assets outside of PCS 12852, such as, but, not limited to, its oncology drug product candidates ("*Excluded Products*").

The "*Territory*" shall be worldwide, excluding the Republic of Korea (South Korea).

The "*Field of Use*" shall mean the diagnosis, treatment and prevention of medical conditions and diseases in humans.

- D. Services: During the Standstill Period, and during the period until the Option Exercise Payment becomes due, Processa will provide (at no cost to Intact) reasonable support with clinical and regulatory planning up to 0.4 FTE where relevant to the Technology. If the support requested by Intact exceeds 0.4 FTE, in Processa's reasonable estimation, the Parties shall negotiate in good faith the costs for the additional work. Nonetheless, after the Option Exercise Payment, subject to Intact and Processa entering into separate agreements (with mutually agreed upon terms and costs/fees), Processa shall provide mutually agreed upon support and consultation services.
- E. Financing
Obligation;
Reversion
Rights:Intact shall raise a total of at least \$10 million in equity
financing for the further development of the Technology
("Financing Obligation") during the Standstill Period or
Standstill Extension. If Intact does not achieve the Financing
Obligation within the Standstill Period or Standstill Extension
Period, there will be no obligation for either Party to enter into
a License Agreement, and the Term Sheet and License
Agreement shall terminate and all granted rights to PCS 12852
and any other rights granted under this Term Sheet and License
Agreement shall revert back to Processa.
- F. Intact
Responsibilities;
Joint Steering
Committee:After the Closing Date, as between Processa and Intact, Intact
assumes responsibility for all efforts and costs associated with
the development, manufacture and marketing of the
Technology and Products.

Development of PCS 12852 and any Products shall be overseen by a Joint Steering Committee ("*JSC*") and additional

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Execution Copy Confidential June 13th, 2025 Intact Processa Option License Binding Term Sheet subcommittees if created by the JSC, as described in more detail in the License Agreement, and would cover research, development, manufacturing, trial protocols, regulatory matters, publications, and other similar matters. The JSC and any subcommittee shall have equal representation from both Intact and Processa. The JSC would operate by consensus. Any escalation and final decision-making processes shall be mutually agreed upon and set forth in more detail in in the License Agreement. G. Patent After the Closing Date, as between Processa and Intact, Intact **Prosecution and** will assume one hundred percent (100%) responsibility and payment of any costs and fees for prosecution and maintenance Fees: of Patent Rights, including, but notwithstanding, any patents (and corresponding patent applications) covering Technology and Products. **H.** Confidentiality: Each of the Parties agree that any confidential information of the other party received in the course of performance under this Term Sheet shall be subject to that certain Confidentiality Agreement, dated April 11, 2024, between Intact and Processa ("Confidentiality Agreement"). Without limiting the generality of the foregoing, all parties shall keep confidential the terms and details of this Term Sheet until the definitive agreements for the exclusive license have been executed; provided that a Party may disclose such information to the extent reasonably necessary to comply with any applicable laws, rules and regulations, including SEC rules and regulations and the rules of the stock exchange upon which a party's shares are traded. In addition, Processa or Intact may disclose terms and details of the Term Sheet to its agents, consultants, accountants, attorneys and other advisors, to potential investors subject to confidentiality obligations, and in a press release ("Press Release") approved in advance by the other Party, and such approval shall not be unreasonably withheld, conditioned or delayed.

> This Term Sheet should only be discussed by and between the senior officers, members of the board of directors of the Parties and others as necessary to accomplish the objectives of this Term Sheet. All such individuals shall be subject to obligations of confidentiality.

I. Expenses Each of the Parties shall be responsible for and bear its own expenses related to the actions necessary to negotiate and execute the definitive agreements contemplated hereby.

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J.	Due Diligence	Subject to the confidentiality provisions herein (as set forth in Section H), each Party will provide access, as reasonably necessary, to its management, consultants, accountants, advisors and all other representatives, and to all their respective properties, clinical, scientific, operating and financial data, records, agreements and other information requested by the other Party that are solely related to the Transaction. For the sake of clarify, if the results of diligence are not to the reasonable satisfaction of either Party, then there will be no obligation for either Party to enter into a License Agreement.
K.	Governing Law; Entire Agreement:	This Term Sheet shall be governed by the laws of Delaware, without regard to its or any other jurisdiction's conflicts of laws principles. For purposes of this Term Sheet, it shall be deemed to have been executed in Delaware. This Term Sheet supersedes all prior discussions and writings and constitutes, with the Confidentiality Agreement, the entire agreement between the Parties with respect to the subject matter hereof. No waiver or modification of this Term Sheet will be binding upon either Party unless made in writing and signed by a duly authorized representative of such Party, and no failure or delay in enforcing any right will be deemed a waiver. In addition, this Term Sheet may be executed in two or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Facsimile and pdf signatures shall have the same legal effect as original signatures.
L.	Dispute Resolution:	Any controversy, conflict or dispute of any nature arising out of or relating to this Term Sheet and the transaction contemplated herein will be settled exclusively and finally by arbitration governed by ICC rules carried out in Delaware, Intact will select one arbitrator to represent it, and Processa will select one arbitrator to represent it, and the two arbitrators together will select a third arbitrator for the proceedings.
M.	Intentions of the Parties:	The Parties acknowledge and agree that this Term Sheet is a binding term sheet and shall constitute an obligation for the Parties to enter into a transaction consistent with the terms set forth herein. The Parties further acknowledge and agree that this Term Sheet does not contain all matters upon which agreement must be reached for the Transaction to be consummated. The Parties shall negotiate in good faith the definitive agreements to consummate such a transaction as promptly as possible.

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Execution Copy Intact Processa Option License Binding Term Sheet		Confidential June 13 th , 2025
	If the Parties are unable to agree on the terms a the License Agreement (other than those set for within thirty (30) days after the Anticipated Ag Effective Date set forth in Section N (License a such terms and conditions shall be determined arbitration in accordance with Section L (Disp	rth herein) greement Agreement), through binding
N. License Agreement:	The Parties agree to negotiate in good faith to or definitive transaction documents (<i>"License Ag</i> respect to the subject matter set forth herein an consistent with this Binding Term Sheet"), wit signing on or prior to August 11 th , 2025 (<i>"Anti Agreement Effective Date"</i>). The License Agr contain customary definitions, representations, covenants.	<i>reements</i> ") with d otherwise h an anticipated <i>cipated</i> reement will
O. Transferability	Prior to Closing, and subject to agreement by b Intact shall have the right to assign, transfer, or convey any or all of its rights and obligations u Sheet to any third party (the "Transferee"), wit for the Holder or the Transferee to pay any add royalties, or other consideration to Processa or provided the third party is reasonably acceptab has achieved (either itself or through a legal an transfer of rights and/or money/capital from In obligations required to have been completed pr and Closing Conditions (including, but, not lim of any amounts owed under this Term Sheet pr and has agreed to assume all obligations in this License Agreements.	otherwise inder this Term hout the need litional fees, any other party, le to Processa, d compliant tact) all ior to Closing nited to, payment ior to Closing),

[Signature Page to Follow]

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IN WITNESS WHEREOF, the Parties hereto have executed this Term Sheet by their duly authorized representatives, effective as of June 11th, 2025 (the "*Effective Date*").

PROCESSA PHARMACEUTICALS, INC.

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— DocuSigned by: Recument

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Signature George Ng Chief Executive Officer 13 June 2025 Signature Ravinder Pamnani Chief Executive Officer 13 June 2025

INTACT THERAPEUTICS

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EXHIBIT A

Milestones, Milestone Payments & Royalties

Development and Regulatory Milestones

Milestone	Milestone Payment
First Patient Dosed in Next Clinical Study	\$500,000
Last Patient Dosed in Next Clinical Study	\$500,000
First Patient Dosed in Phase 3 trial	\$2,000,000
Last Patient Dosed in Phase 3 trial	\$2,000,000
1st NDA approval	\$4,000,000
2nd NDA approval	\$4,000,000
1st Ex-US approval	\$4,000,000
2nd Ex-US approval	\$3,000,000

Commercial milestones

Worldwide Annual Accrued Net Sales	Milestone Payment	
≥\$50M	\$2,500,000	
≥\$100M	\$5,000,000	
≥ \$250M	\$12,500,000	
≥\$500M	\$25,000,000	
≥ \$750M	\$37,500,000	
\geq \$1 Billion	\$50,000,000	
\geq \$2 Billion	\$100,000,000	
\geq \$5 Billion	\$200,000,000	

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Processa Pharmaceuticals Signs Binding Term Sheet Granting Intact Therapeutics Exclusive Option to License Phase 2 Gastroparesis Drug Candidate

\$452.5 million in total milestone payments \$2.5 million in near-term payments Double-digit royalties on future net product sales 3.5% equity stake in Intact Therapeutics

HANOVER, Md., June 17, 2025 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), today announced that it has entered into a binding term sheet with Intact Therapeutics, Inc. ("Intact") granting Intact the exclusive option to license PCS12852, a best-in-class 5-HT4 receptor agonist with the potential to become a first meaningful treatment for gastroparesis and other gastrointestinal motility disorders.

Under the terms of the agreement, Processa is eligible to receive a \$2.5 million option exercise fee, up to \$20 million in development and regulatory milestone payments and over \$432.5 million in commercial milestone payments based on net product sales. Intact will also pay Processa a double-digit royalty on worldwide net sales of licensed products, excluding South Korea, and provide Processa with an equity stake in Intact upon closing. Under the terms of its license, Processa must share 60% of any cash payments with its licensor (excluding the equity stake in Intact).

"This agreement is another example of how we can unlock the value of our non-oncology assets while remaining laser-focused on our mission of developing next-generation cancer therapies," said George Ng, CEO of Processa. "We believe Intact's innovative delivery platform and GI-focused strategy make them an ideal partner to advance PCS12852 toward commercialization. PCS12852 has demonstrated a favorable safety and efficacy profile in clinical studies and represents a highly differentiated, potentially best-in-class approach for patients suffering from gastroparesis and other gastrointestinal disorders."

"At Intact, we are building a company around the idea that there remain significant unmet clinical needs in GI — not only to treat disease but also to radically improve patient quality of life," added Ravi Pamnani, CEO and Co-Founder of Intact Therapeutics. "PCS12852's strong clinical data in improving gastric motility and clean safety profile make it an ideal candidate to add to our GI portfolio. We are thrilled to partner with Processa and advance this asset through our development pipeline."

PCS12852 is a selective 5-HT4 receptor agonist that completed a Phase 2a trial demonstrating strong safety, tolerability, and efficacy signals in patients with diabetic gastroparesis. Gastroparesis is a debilitating condition affecting gastric motility with limited treatment options and high unmet need. PCS12852 is designed to restore normal gastric emptying without the cardiovascular and central nervous system side effects seen with older agents in this class.

Lorin K. Johnson, Ph.D., Board Member and Scientific Advisor to Intact Therapeutics, stated, "The safety profile and high selectivity of PCS12852 make it a promising therapeutic option for patients with a wide range of GI motility disorders. The partnership between Intact and Processa will provide strategic alignment and shared upside to create value for both companies."

The exclusive license will become effective upon completion of the definitive agreements and satisfaction of closing conditions, including an amendment of the license agreement between Processa and its licensor.

About Intact Therapeutics, Inc.

Intact Therapeutics is a clinical-stage biopharmaceutical company pioneering next-generation therapies for gastrointestinal (GI) disease, including products leveraging its proprietary thermal hydrogel technology. Intact spun out of Stanford University, and investors include Y Combinator, Encube Ethicals, and Brightstone Capital. The company has also received several non-dilutive grants from the NIH, NSF, and the California Institute of Regenerative Medicine, to further expand its treatment pipeline.

For more information, visit www.intacttherapeutics.com.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Cancer (NGC) drugs with improved safety and efficacy. Processa's NGC drugs are modifications of existing FDA-approved oncology therapies resulting in an alteration of the metabolism and/or distribution of these drugs while maintaining the existing mechanisms of killing the cancer cells. By combining its novel oncology pipeline with proven cancer-killing active molecules and its Regulatory Science Approach, Processa's strategy is to develop more effective therapy options with improved tolerability for cancer patients through an efficient regulatory path.

For more information, visit our website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties, which include, but are not limited to, statements regarding the Company's expectations regarding the entry into a definitive license agreement with Intact. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

Company Contact:

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Investor Relations:

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