

**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 27, 2025

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

45-1539785
(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 ☐

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 27, 2025, Processa Pharmaceuticals, Inc. (the "Company") invoked its right to terminate the Licensing Agreement between Ocuphire Pharma, Inc., (now Opus Genetics) dated June 16, 2021.

Item 7.01. Regulation FD Disclosure.

On July 1, 2025, the Company issued a press release announcing strategic portfolio review and pipeline realignment to maximize shareholder value. 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
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10.1	Termination of Licensing Agreement dated June 27, 2025.
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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 July 1, 2025.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: /s/ George Ng
George Ng
Chief Executive Officer



27 June 2025

Mr. George Magrath
Chief Executive Officer
Opus Genetics, Inc. (previously Ocuphire Pharma, Inc.)
8 Davis Drive, Suite 220
Durham, NC 27709

Re: Termination of Licensing Agreement

Dear Mr. Magrath:

Effective today, Processa Pharmaceuticals is invoking its right to terminate the Licensing Agreement between Ocuphire Pharma, Inc., and Processa Pharmaceuticals, Inc., dated June 16, 2021 [“License Agreement”), and this is Processa’s notice of termination of the License Agreement.]. As per section 11.2 of the Agreement, Processa may terminate the [License Agreement] by providing 120 days’ written notice.

Processa rescinds all rights and licenses previously granted to us. We shall return any original documents in our possession and/or destroy any copies, if requested.

We kindly request that you review and sign the Notice of Termination of License Agreement and Acknowledgement of Receipt of our request to terminate.

Should you have any issues, questions, or concerns regarding this, please feel free to reach out to us.

Kind regards,

Wendy Guy
Chief Administrative Officer

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

**NOTICE OF TERMINATION OF LICENSE AGREEMENT
AND
ACKNOWLEDGEMENT OF RECEIPT**

This notice of Termination of License Agreement and Acknowledgement of Receipt is made as of this 27 day of June 2025 by Processa Pharmaceuticals, Inc., (Processa) a Delaware corporation, having its principal place of business at 601 21st Street, Suite 300, Vero Beach, FL 32960 and Ocuphire Pharma, Inc., (Ocuphire) a Delaware Corporation having its principal place of business at 8 Davis Drive, Suite 220, Durham, NC 27709. Each of Processa and Ocuphire may be referred to as a Party, and collectively as the Parties.

WHEREAS the Parties entered into a License Agreement effective as of June 16, 2021 ("License Agreement"); and

WHEREAS Processa desires to give Notice of Termination of the License Agreement, effective as of June 27, 2025; and

WHEREAS Ocuphire is prepared to provide an Acknowledgement of Receipt of Notice of Termination of License Agreement.

Therefore, the Parties agree:

1. Pursant to Section 11.2 of the License Agreement, Processa gives 120 days written Notice of Termination of the License Agreement as of June 27, 2025 ("the Termination Date").
2. Processa and Ocuphire acknowledge that the Notice delivery provisions of Section 11.2 of the License Agreement are deemed satisfied upon the signature of the Parties to this Notice of Termination of License Agreement and Acknowledgement of Receipt.
3. This Notice of Termination and License Agreement and Acknowledgement of Receipt may be executed in counterparts and each counterpart shall be deemed an original.

The parties have caused this notice of Termination of License Agreement and Acknowledgement of Receipt to be executed by their duly authorized representations below.

Processa Pharmaceuticals, Inc.


Wendy Guy

Chief Administrative Officer

Opus Genetics, Inc.

George Magrath
Chief Executive Officer

Processa Pharmaceuticals Provides Portfolio and Business Update

- Signed binding term sheet granting Intact Therapeutics an exclusive option to license PCS12852
- Continue enrolling patients in Phase 2 study of PCS6422
- Strengthened balance sheet with \$7M capital infusion

VERO BEACH, Fla., July 1, 2025 (GLOBE NEWSWIRE) — **Processa Pharmaceuticals, Inc. (Nasdaq: PCSA)**, a clinical-stage pharmaceutical company developing next-generation cancer therapies, provides updates on its product pipeline, upcoming milestones and business activities.

“We are taking deliberate steps to focus our resources on programs with the highest potential for clinical success and commercial impact,” said Dr. David Young, President Research and Development at Processa. “Our approach continues to center on developing safer, more effective treatments for cancer while creating value through strategic business development and disciplined pipeline management.”

“Our NGC-Cap Phase 2 clinical trial in metastatic breast cancer is actively enrolling patients. We continue to anticipate sharing initial data in the second half of 2025,” said George Ng, Chief Executive Officer of Processa Pharmaceuticals. “The streamlining of our development pipeline, signing of strategic partnerships, and optimizing our capital allocation, enable us to make the necessary investments in our science in order to enhance shareholder value.”

Key Portfolio Updates:

- **PCS6422 (NGC-Cap):** PCS6422, Processa’s lead oncology asset in combination with capecitabine (NGC-Cap), is actively enrolling patients in a Phase 2 study for metastatic breast cancer. The program remains a top priority, with the remaining patients needed for the pre-planned interim analysis expected to be enrolled in the second half of 2025. The trial builds on compelling safety and efficacy signals observed in earlier studies, including improved tolerability and increased exposure to active cancer-killing metabolites.
- **PCS499:** Based on preliminary positive results in kidney disease and the FDA allowing surrogate endpoints to now be used in rare kidney diseases, Processa is currently designing a new adaptive pivotal PCS499 Phase III study to discuss with the FDA later this year. In addition, Processa is establishing a dedicated subsidiary to hold PCS499. The move is intended to enhance strategic flexibility in targeting capital raising and potential partnership exploration after meeting with the FDA.
- **PCS12852:** As previously announced, Processa has signed a binding term sheet with Intact Therapeutics, Inc. granting an exclusive option to license PCS12852 for gastroparesis and related gastrointestinal motility disorders. Under the terms, Processa is eligible for up to \$454 million in milestone payments, a 12% royalty on future sales, and a 3.5% equity stake in Intact. The partnership represents a strategic monetization of non-core assets while maintaining upside potential.
- **PCS11T:** PCS11T is Processa’s preclinical oncology asset based on the active metabolite of irinotecan. The company continues to define and explore preclinical and clinical development strategies as well as opportunities to support future development.
- **PCS3117:** After determining that the time and cost required to advance PCS3117 to a meaningful milestone would be too high, Processa has terminated the license agreement for PCS3117 and returning the rights to the original licensor.

Commitment to Shareholder Value

These portfolio changes align with Processa’s strategic intent to focus on oncology assets with strong differentiation, scientific rationale, commercial opportunity and clear regulatory pathways. The company believes this will optimize our human and capital resources, expedite the unlocking of hidden asset value through partnerships, and position the organization to deliver long-term shareholder returns.

Investor Webinar

Processa CEO George Ng will participate in a live investor webinar on Wednesday, July 9, 2025, at 4:15 p.m. ET to discuss the company’s strategic pipeline realignment and value-creating milestones.

To register for the free webinar, please visit:

<https://www.redchip.com/webinar/PCSA/85765532754>

Questions can be pre-submitted to PCSA@redchip.com or online during the live event.

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. In addition to its core oncology programs, Processa is actively pursuing strategic partnerships for non-oncology assets to unlock additional value.

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. 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:

Patrick Lin
(925) 683-3218

plin@processapharma.com

Investor Relations:

Dave Gentry
RedChip Companies, Inc.
1-407-644-4256
PCSA@redchip.com
