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 9, 2021

PROCESSA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39531**	**45-1539785**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland, 27106
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (443) 776-3133

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, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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 7.01. Regulation FD Disclosure.

Processa Pharmaceuticals, Inc. ("***Processa***") will present on June 9, 2021 and participate in virtual meetings with analysts and investors at the LD Micro Invitational XI June 8-10, 2021. During these virtual meetings, Processa's presentation will be uploaded into a portal, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation will also be made available in the "Investors" section on Processa's website, located at www.processapharmaceuticals.com.

Processa undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Processa's website. Processa routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Exhibit Description**
99.1	June 2021 Corporate Presentation

SIGNATURES

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.

PROCESSA PHARMACEUTICALS, INC.

Date: June 9, 2021

By: */s/ David Young*
David Young
Chief Executive Officer

Processa Pharmaceuticals

LD Micro Invitational
June 9, 2021

David Young, PharmD, PhD
Chairman and CEO

Disclaimer: Forward Looking Statements

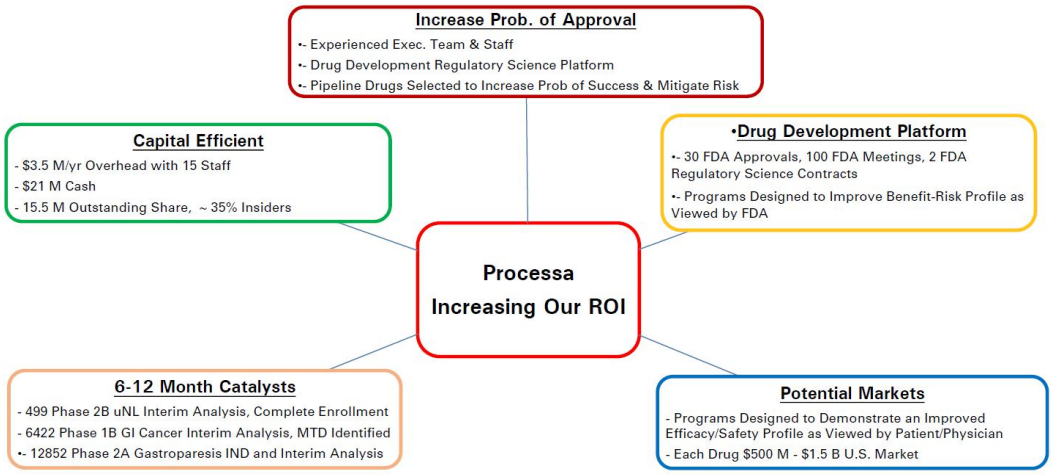
The following summary is provided for informational purposes only and does not constitute an offer or solicitation to acquire interests in the investment or any related or associated company.

The information contained here is general in nature and is not intended as legal, tax or investment advice. Furthermore, the information contained herein may not be applicable to or suitable for an individual's specific circumstances or needs and may require consideration of other matters. The Company and its directors, officers, employees and consultants do not assume any obligation to inform any person of any changes or other factors that could affect the information contained herein.

These materials may include forward-looking statements including financial projections, plans, target and schedules on the basis of currently available information and are intended only as illustrations of potential future performance, and all have been prepared internally.

Forward-looking statements, by their very nature, are subject to uncertainties and contingencies and assume certain known and unknown risks. Since the impact of these risks, uncertainties and other factors is unpredictable, actual results and financial performance may substantially differ from the details expressed or implied herein. 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. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.

Processa Highlights



Processa Capital Structure and Share Information on March 31, 2021

- **Stock Listing:** PCSA – NASDAQ
- **52 Week Low-High:** $3.95 - $13.15
- **Price (June 7, 2021):** $6.51
- **Market Cap (June 7, 2021):** $101,045,720
- **Shares Outstanding:** 15,521,616
- **Fully Diluted Shares:** 16,511,147
- **Cash, Cash Equivalents:** $23,048,000
- **Expected 2021 Overhead Cash Burn, Including Salaries:** $3,500,000
- **Employees:** 15
- **Research Analyst Reports:**
  Robin Garner – Craig Hallum
  Aydin Huseynov MD, CFA - Benchmark
  Hogan Mullaly – Encode Ideas

Processa Pipeline – Multiple Opportunities For Success

Pipeline of Drugs to Treat Patients who Need Better Treatment Options

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Market Size
PCS499	Ulcerative Necrobiosis Lipoidica			Phase 2B FPI May		> $1 B
PCS6422	Metastatic Colorectal, Breast Cancer		Phase 1B FPI June			> $1 B
PCS12852	Gastroparesis, Functional Constipation			Phase 2A FPI 1Q'22		> $1 B
PCS11T	Small Cell Lung, Colorectal Cancer	IND 2022				> $1 B

Processa's Risk Abated Approach and Criteria for Drug Selection

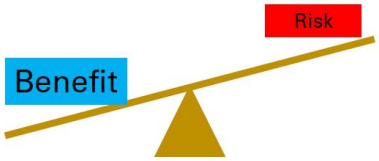
Experience in Adding Value to Companies: > 30 FDA Approvals & Regulatory Science Contracts from FDA

DEVELOP NOT **DISCOVER**

REGULATORY SCIENCE PLATFORM

Unmet Medical Need	+	Efficacy Evidence	+	Regulatory Science	+	Capital Efficiency	+	Potentially High ROI
• Clear and obvious **patient need** • **Favorable competitive** dynamics		• **Evidence of clinical efficacy** in targeted medical condition • **Higher** probability of **successful development**		• **Improve Benefit/Risk** profile that FDA evaluates for approval • **Optimize trial design** and **anticipate** what **FDA** requires for approval (Trifecta: decreasing risk, time to approval & cost)		• **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.) • **Efficient development** program and clinical trial design		• **Intelligently monetize and partner assets**

Regulatory Science Approach



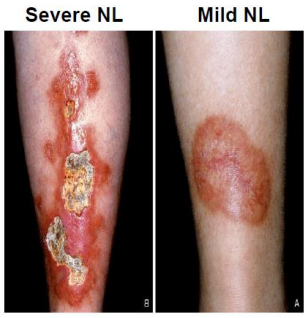
Regulatory Science Approach

- Program Designed to Improve Benefit-Risk Profile to Meet FDA Requirements and Patient/Physician Requirements
- Program and Clinical Trials Anticipate FDA Requirements for Approval
- Interact Collaboratively with FDA While Negotiating Program

Increase Benefit & Efficacy ← → Decrease Risk & Safety

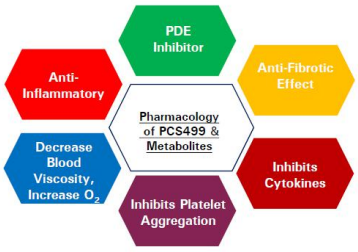
Example 1: Ulcerative Necrobiosis Lipoidica (uNL)

- **Skin, tissue below the skin becomes necrotic**, can last from months to years with complications such as infections, amputation, and cancer
- **70%** of the patients are women between 20 – 60 years old; **60% of NL patients are diabetic** but NL is not dependent on glucose control and is **not the same histologically as diabetic ulcers**
- **30% of NL patients have painful ulcers occurring naturally or from contact trauma to the lesion**
- Patients seen by primary care, endocrinologist, dermatologist
  - Diagnosis requires a biopsy to demonstrate histopathology of these lesions is NL
- **Natural complete healing of moderate to severe ulcers** during the first 1-2 years after onset occurs **in less than 5% of these patients**



Unmet Medical Need, Evidence of Clinical Efficacy, PCS499 Improves Benefit-Risk

- **No FDA approved treatment** for uNL or NL, no standard of care, all treatments are inadequate
- **Drugs have been used off-label with mixed success** (e.g., **pentoxifylline (PTX)**) - side effect profile, limited efficacy
- **PCS499 is the deuterated analog of the major metabolite of PTX**; has identical metabolites and pharmacological targets but the **PK of 499 and its metabolites is different resulting in a different efficacy and safety profile than PTX**

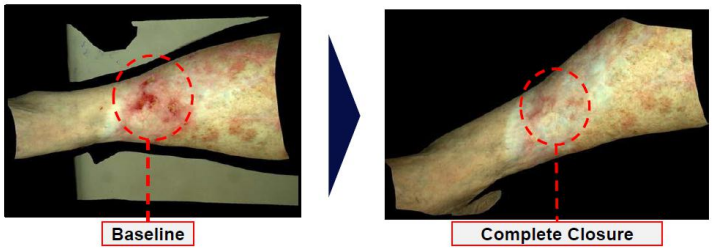


Pathophysiological Changes in NL

- **Decrease in blood flow & Oxygenation**
- **Decrease in platelet survival**
- **Increase inflammation**
- **Increase fibrosis**
- **Increase cytokines**
- **Degeneration collagen**
- Alters fat deposition

Phase 2A PCS499 Improves Benefit-Risk Profile

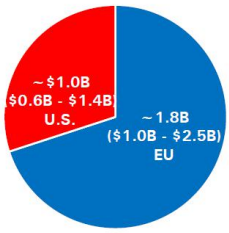
- In a study of 10 NL and 2 ulcerative NL patients, **all ulcers closed** in the 2 ulcerative NL patients, **including new contact trauma ulcers**
- Non-ulcerated patients reported improvement in NL but clinical significance could not be determined
- **1.8 gm/d of 499 was well tolerated in the 12 patients**



Ulcerative NL (uNL) Target Population

- **Economic Value: Initial Markets**
  - 75,000 – 185,000 NL patients in U.S.
  - **22,000 – 55,000 uNL patients in U.S.**
  - Presently no approved treatment and off-labeled drugs have not been proven to be significantly effective/safe in patients with NL or uNL
  - **499 has orphan designation for NL (7-year market exclusivity)**
  - 499 would be the first approved drug to treat patients with uNL or NL
  - **U.S. market potential in uNL is ~ $1 B annual gross sales**

Ulcerative Necrobiosis Lipoidica (uNL)
Max Gross Sales



- **22,000 – 55,000 uNL Patients in US**
- **150,000 – 400,000 uNL Patients Worldwide**

PCS499 FDA Designated Orphan Drug - Ulcerative Necrobiosis Lipoidica (uNL)

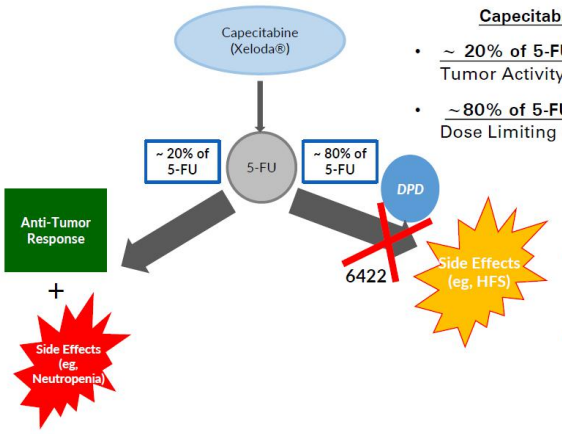
- **Phase 2B to Better Define Variables for Phase 3:**
  - **General Design:** Randomized, double-blind, placebo-controlled trial of 1.8 gm/d of 499 in 20 uNL patients with primary efficacy evaluation at 6 months
  - **Objective:** To determine complete closure response rate of ulcers in patients on placebo vs 499
  - **Inclusion Criteria Examples:** Biopsy-confirmed diagnosis of ulcerated NL; at least one (1) ulcer with a minimum surface area of 1 cm^2, total ulcer area of a minimum of 2 cm^2, and no more than 6 ulcers
  - **Exclusion Criteria Examples:** In the last 6 weeks took other drugs such as oral corticosteroids, topical drugs, systemic pentoxifylline, theophylline, immunosuppressant or immunomodulatory drugs

- **First patient has been randomized and dosed**
- Clinical sites being initiated and will be adding more sites
- **Interim Analysis 1Q'22**
- **Final Analysis 2H'22**

Next Trial
Phase 3 in 2023 Under Special Protocol Assessment

Example 2: PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®)

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



Capecitabine Converts to 5-FU in the body

- ~ 20% of 5-FU Metabolizes to Molecules with Anti-Tumor Activity and side effects such as neutropenia
- ~80% of 5-FU Metabolizes to Molecules that Cause Dose Limiting Side Effects with no efficacy

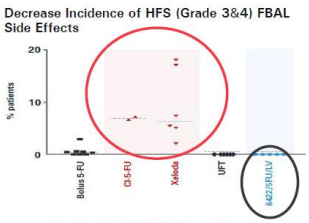
6422 Inhibits DPD Allowing Two Ways to Win

- Lower Side Effects by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- Improve Capecitabine Efficacy – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

Unmet Medical Need and Evidence of Clinical Benefit

➢ **Safety Differentiation of 6422 + Capecitabine vs Existing Cancer Chemotherapy**

- 50-70% of capecitabine patients have adverse events from FBAL resulting in decreasing capecitabine dose or stopping chemotherapy
- Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination will **decrease FBAL related adverse events**



Revollo et al. 2008 Clin Cancer Res;
Masuda et al. 2017. NEJM

Unmet Medical Need, Evidence of Clinical Benefit, Regulatory Science Platform

➢ **Efficacy Differentiation of 6422 + Capecitabine vs Existing Cancer Chemotherapy**

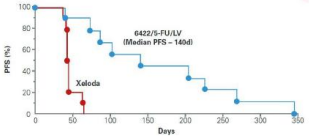
- ~30% of patients do not respond at all to capecitabine and ~30% are partial responders
- Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination may **extend progression free survival (PFS) in patients who do not respond to capecitabine as well as increase PFS in those patients who do respond**

➢ **Regulatory Science**

- **Treatment of metastatic colorectal cancer**
- **Measuring biomarker(s)** may help to increase probability of successful treatment
- 6422+capecitabine combination **provides patients with a better benefit-risk profile (less adverse events and/or better efficacy) than just capecitabine**

Improve Capecitabine Efficacy with 6422:

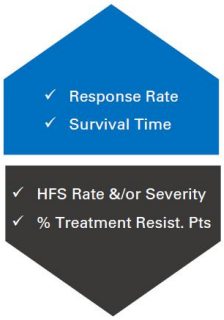
Lower Dose of 6422 Administered Hours Before 5-FU/LV in Capecitabine Resistant Patients



5-FU = 5-Fluoruracil; LV = Leucovorin;
PFS = Progression Free Survival, SD = Stable Disease; PR = Partial Response; PD = Progressive Disease

Adherex files & Rivera E et al, 2014. Clin. Breast Cancer

PCS6422 - Capecitabine Combination Different than Capecitabine



➢ **Economic Value: Initial Markets**

- 6422 + Capecitabine combination potential 1st line therapy for a number of cancers (e.g., metastatic colorectal and breast cancer)
- Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total colorectal cancer patients worldwide
- Breast cancer; > 275,000 new patients/yr U.S., > 2.0 M total patients with breast cancer worldwide
- > 45% of the new patients with colorectal cancer presently receive capecitabine
- Potential for 6422+capecitabine combination to **replace capecitabine in treatment of colorectal cancer and other cancers**
- **U.S. market potential in colorectal cancer is $700 M - $1.5 B**

PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®)

➢ **Present Phase 1B Trial to Determine Appropriate Dosing of 6422 and Capecitabine**

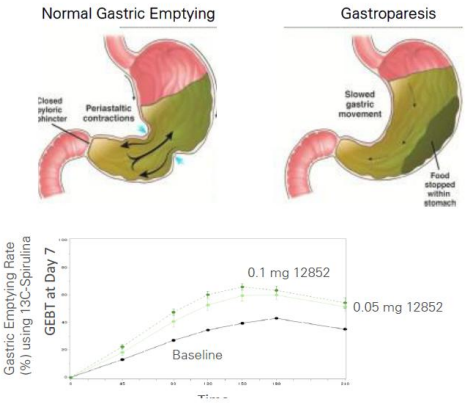
- **General Design:** MTD Stage 1 will be a 3+3 cohort capecitabine trial after a single safe dose of 6422; 1 dose 6422, 7d of capecitabine, 7d of no capecitabine; up to 6 cohorts of capecitabine b.i.d. at 75mg/d to 600 mg/d followed; followed by Stage 2 dose confirmation of the MTD
- **Objective:** To determine safe maximum tolerated dose of capecitabine after single safe dose of 6422
- **Inclusion Criteria Examples:** Advanced, metastatic or unresectable refractory GI cancer; not received treatment with 5-FU or capecitabine in 4 weeks; life expectancy > 12 wks
- **Exclusion Criteria Examples:** Has current brain metastasis, has clinically significant cardiac condition; self-reported to be DPD enzyme deficient
- **Key Additional Information:** *Evaluation of potential biomarkers*

➢ Initiating Clinical Sites
➢ MTD Stage 1: **1st Patient Expected to Enroll in June**
➢ MTD Stage 1: **Interim Analysis 3-4Q'21**, Final Analysis 2-3Q'22
➢ Dose Confirmation Stage 2: 1st Patient Expected 2H'22, Final Analysis 2023/2024

Next Trial
Phase 2/3 Trial in 2023-2024

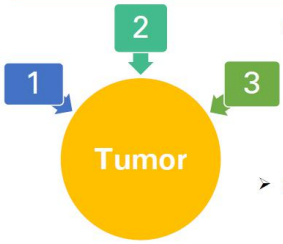
PCS12852 Potent-Selective 5HT4 Agonist: Gastroparesis ($1 B Market)

Submit IND for Phase 2A Trial in 3Q'21, FPI in 1Q'22



	12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Binding	• Very specific 5HT4 Agonist • Very potent to 5HT4	• Less specific binding to 5HT4 than 12852 • Less potent than 12852	• Binds to Dopamine D2 receptors
Side Effects	• **No serious side effects** in clinical studies to date	• **Serious CV side effects** (e.g., cisapride removed from market) • Suicidal ideation	• Black Box Warning **serious neurological side effects**
Efficacy	• Increase gastric emptying rate • **Gastroparesis patient study required**	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug approved for treatment of gastroparesis

Regulatory Science Approach Helps to Select Drugs for Pipeline



Successful Treatment of Cancer Depends on Many Factors Including a Patients Genetic Make-up and the Biological Differences Between the Tumor and Normal Tissue

- Potential Phase 2B/3 Acquisition (Drug X):
  - Prior trials showed Drug X was not any better than existing cancer therapy
  - Study design appropriate? Treat all patients or treat an enriched population?
  - Drug X likely improves benefit-risk profile for some patients but not all patients
  - Identified potential biomarker(s) that increase probability patients respond to Drug X
  - Potentially beneficial as 1st line therapy in numerous cancers or 2nd line therapy in patients resistant to present treatment, providing a > $1B market
  - Phase 2B trial with existing IND followed by single Phase 3

Summary Timeline of Pipeline and Key Clinical Catalysts

	1H 2021	2H 2021	1H 2022	2H 2022	2023-2025
PCS499 Phase 2B	• Initiate Sites • **FPI (May)**		• **Interim Analysis**	• **Final Analysis**	• **Phase 3 Trial** • **NDA Submission**
PCS6422 Phase 1B	• Initiate Sites • **FPI (June)**	• **Interim Analysis (Sept-Oct)**	• **Final Analysis MTD Stage 1**	• **Initiate Dose Confirmation Stage 2**	• **Final Analysis Stage 2** • **Phase 3 Trial**
PCS12852 Phase 2A	• Pre-IND Meeting • Prepare IND	• **IND Safe to Proceed (Sept-Oct)** • Initiate Sites	• **FPI (1Q'22)**	• **Interim Analysis**	• **Final Analysis** • **Phase 2B Trial** • **Phase 3 Trial**
PCS11T IND	• Evaluate CMOs	• Initiate Preliminary CMC	• Initiate Tox		• Complete Tox • Complete IND • **IND Safe to Proceed**

FPI – First Patient In
CMO – Contract Manufacturing Organization
CMC – Chemistry, Manufacturing, Control

Bold & Underlined = Key Clinical Catalysts
Red, Bold, Underlined = Key Clinical Catalyst Achieved

Our People Lead to Success

Management Team

David Young, PharmD. PhD
Chief Executive Officer, Chairman of the Board

Sian Bigora, PharmD.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Patrick Lin
Chief Business – Strategy Officer

James Stanker, CPA
Chief Financial Officer

Wendy Guy
Chief Administrative Officer

Board of Directors

David Young, PharmD. PhD
Chairman of the Board, CEO

Justin Yorke
Independent Director
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

Geraldine Pannu
Independent Director
Founding and Managing Partner of GLTJ Pioneer Capital

Virgil Thompson
Independent Director
Former Chairman of the Board, Questcor Pharmaceuticals

Khalid Islam, PhD
Director
Former CEO of Gentium
Chairman of the Board of Fennec Pharm.