# 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): May 10, 2023

#### MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-38022 (Commission File Number) 46-3011414 (IRS Employer ID Number)

1545 Route 206 South, Suite 302 Bedminster, New Jersey (Address of principal executive offices)

07921 (Zip Code)

Registrant's telephone number, including area code: (908) 484-8805

Not Applicable (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 (see General Instruction A.2. below):

- □ 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	Name of Each Exchange on Which Registered			
Common Stock	MTNB	NYSE American			

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.  $\Box$ 

#### Item 2.02. Results of Operations and Financial Condition.

On May 10, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "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 (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### Item 7.01 Regulation FD Disclosure.

On May 10, 2023, the Company issued a press release announcing, among other things, an update on certain of its strategic initiatives and programs. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The Company updated its corporate presentation (the "Corporate Presentation") which it intends to use at various conferences and investor meetings. The Corporate Presentation is attached hereto as Exhibit 99.2 and incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 and 99.2 attached hereto shall not be deemed "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 shall be expressly set forth by specific reference in such a filing.

#### Item 8.01. Other Events.

On May 10, 2023, the Company announced an update on certain of its programs and initiatives, including the following:

- The Company intends to complete its funding proposal submissions to the Biomedical Advanced Research and Development Authority and the National Institutes of Health through the Advanced Research Project Agency for Health during the second quarter of 2023;
- The Company's initial *in vivo* study of oral mRNA delivery conducted in collaboration with BioNTech SE did not demonstrate oral preclinical activity. This formulation had successfully delivered mRNA *in vitro* in multiple cell lines prior to advancing to an in vivo study in healthy mice. Additional internal *in vivo* studies of similar non-lipid nanocrystal ("LNC") mRNA formulations did show activity when administered systemically (intramuscularly and intraperitoneally). In addition, these formulations have demonstrated a high degree of stability to at least 17 weeks at 4° Celsius which compares favorably to lipid nanoparticles ("LNPs"). The research collaboration between Matinas and BioNTech SA has been concluded;

- The Company plans to submit a revised Phase 3 trial design in the second quarter of 2023 to assess the safety, efficacy, and tolerability of its MAT2203 product candidate in patients with serious, life-threatening invasive fungal infections ("IFIs"), including patients with limited treatment options. The main cohort in this trial will be in patients with aspergillosis and designed as a non-inferiority comparison to standard-of-care IV azole antifungal patients. This main cohort is expected to include both first- and second-line patients, and its design will likely include an early step-down to oral treatment with MAT2203 administered as monotherapy. The trial will also likely include an additional open-label cohort of patients with a broad range of proven or probable IFIs with limited treatment options who are not able to step down to an oral azole. The open-label cohort study is expected to support label expansion beyond aspergillosis under a 505(b)(2) regulatory pathway and will include patients with invasive mucormycosis, other rare mold infections, invasive candidiasis, candida cystitis, and endemic mycoses including coccidioidomycosis, histoplasmosis and blastomycosis;
- Based on the U.S. Food and Drug Administration's most recent feedback, the Company is re-evaluating a previously contemplated Phase 3 trial of MAT2203 in cryptococcal meningitis ("CM"). The Company believes that a smaller, more focused trial in CM may satisfy regulatory requirements for an additional indication for the treatment of CM;
- To date, seven patients with various IFIs have been treated with MAT2203 under the Company's Compassionate Use Program. Clinical data in these limited cases demonstrated that orally administered MAT2203 is targeted, safe and effectively eradicates IFIs in the most challenging cases. Under the Compassionate Use Program, MAT2203 successfully treated serious infections throughout the body, including bone, central nervous system, lung, sinus, bladder, and skin;
- The Company is working toward the generation of *in vitro* data from an internal program for the delivery of silencing RNA (siRNA) therapies utilizing its LNC platform technology. Initial formulation data are expected in the third quarter of 2023. This program is expected to continue with multiple *in vivo* biodistribution and animal efficacy studies in the second half of 2023; and
- The Company's collaborative research program with National Resilience, Inc. ("National Resilience") was expanded to focus on *in vitro* and *in vivo* testing with mRNA, with the Company and National Resilience focusing on reporter and therapeutic oligonucleotide delivery; both *in vitro* and *in vivo* delivery against reference LNPs with initial data expected in the third quarter of 2023.
- Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second half of 2024.

#### Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the collaboration with National Resilience, the potential of its LNC and PS-NP platform delivery technologies, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, the Company's ability to obtain additional capital to meet its liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; the ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. The Company's product candidates are all in a development stage and are not available for sale or use.

#### Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 10, 2023
99.2	Corporate Presentation, dated May 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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#### **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.

#### MATINAS BIOPHARMA HOLDINGS, INC.

Dated: May 10, 2023 By: /s/Jerome D. Jabbour

Name: Jerome D. Jabbour
Title: Chief Executive Officer

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# Matinas BioPharma Reports First Quarter 2023 Financial Results and Provides a Business Update

FDA feedback from Type B meeting reiterated the Agency's intent to work collaboratively in advancing development of MAT2203 for the treatment of invasive fungal infections (IFIs)

Phase 3 trial design is being finalized to support a broad label for IFIs under a 505(b)(2) regulatory pathway

Initial in vivo study of oral mRNA delivery did not demonstrate preclinical activity; research under the collaboration agreement with BioNTech has been concluded

Successful in vivo systemic delivery and activity of mRNA in multiple additional studies

Conference call begins at 4:30 p.m. Eastern time today

BEDMINSTER, N.J. (May 10, 2023) – <u>Matinas BioPharma</u> (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, reports financial results for the three months ended March 31, 2023 and provides a business update.

"Feedback from our U.S. Food and Drug Administration (FDA) Type B meeting held in April was encouraging, with the Agency recognizing the significant clinical potential and medical need for an oral, well-tolerated, broad-spectrum amphotericin B product to combat the growing threat of invasive fungal infections," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "The final meeting minutes reflect the FDA's interest in continuing to work collaboratively with Matinas to benefit patients in need and provided us with valuable direction on designing a Phase 3 IFI trial. We are diligently working to finalize a protocol and accompanying statistical package that we believe will support the broadest possible label for MAT2203 for the treatment of IFIs under a streamlined 505(b)(2) regulatory pathway."

"We are pleased with the continued interest from potential partners and funding sources to advance the development of MAT2203. We plan to accelerate our ongoing business development discussions and submit our funding proposals to the Biomedical Advanced Research and Development Authority (BARDA) and through the Advanced Research Project Agency for Health (ARPA-H), a new research funding agency within the National Institutes of Health (NIH) that supports high-impact research to drive biomedical breakthroughs, during the second quarter," he added.

"Our initial *in vivo* study of oral mRNA delivery, which was based upon encouraging early *in vitro* results, and conducted with our collaborator BioNTech, did not demonstrate preclinical activity. While disappointing, we recognize that this was an ambitious goal for a first *in vivo* study of a new, unique mRNA formulation, where, to date, no delivery technology has been successful in achieving oral delivery of mRNA. We are pleased these formulations showed activity when administered systemically in other internal studies, in addition to demonstrating prolonged stability out to 17 weeks at 4° Celsius. We continue to believe that our technology has potential to provide differentiated delivery of nucleic acids and are in the process of generating additional data in this area both through our collaboration with National Resilience which has expanded to include mRNA following the expiration of exclusivity with BioNTech, and with our internal discovery programs in the siRNA space," Mr. Jabbour concluded.

#### Key Program Updates and Anticipated Upcoming 2023 Milestones

#### MAT2203 (Oral Amphotericin B) Program

#### MAT2203 Phase 3 Trial Design

- The Company plans to submit a revised Phase 3 trial design in the second quarter of 2023 to assess the safety, efficacy, and tolerability of oral MAT2203 in patients with life-threatening IFIs, including patients with limited treatment options. The FDA has indicated support for a trial in aspergillosis that is designed as a non-inferiority comparison to standard-of-care IV azole antifungal treatments. The main cohort in this trial is expected to include both first- and second-line patients, and its design will likely include an early step-down to oral treatment with MAT2203 administered as monotherapy. The trial will also likely include an open-label cohort of patients with a broad range of proven or probable IFIs who otherwise have limited treatment options and are not able to step down to an oral azole. The open-label cohort is expected to support label expansion beyond aspergillosis under a 505(b)(2) regulatory pathway and will include patients with invasive mucormycosis, other rare mold infections, invasive candidiasis, candida cystitis, and endemic mycoses including coccidioidomycosis, histoplasmosis and blastomycosis.
- Based on FDA's most recent feedback, the Company is re-evaluating the specifics of the
  previously contemplated Phase 3 trial in cryptococcal meningitis (CM). The Company believes
  that a smaller, more focused trial in CM, funded by the NIH could satisfy the FDA's requirement
  for an additional indication for the treatment of CM.

#### Compassionate Use Program

- A MAT2203 compassionate use case study was presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) highlighting the use of MAT2203 in a patient with a rare and challenging R. mucilaginosa infection of the bone (osteomyelitis), which placed her at risk for amputation and historically has usually required long-term amphotericin B treatment. The patient was transitioned to MAT2203 under the Company's Compassionate Use Program after suffering significant electrolyte abnormalities and associated renal toxicity related to treatment with IV amphotericin B. Following the transition to oral MAT2203, the patient's renal function returned to normal, and she was able to use MAT2203 safely for six months, leading to a robust clinical response, avoidance of amputation, and a return to full mobility.
- To date seven patients with various IFIs have been treated with MAT2203 under the Company's Compassionate Use Program. Inbound requests have been received from physicians at the NIH, University of Michigan, Nationwide Children's Hospital and Johns Hopkins University on behalf of patients with no treatment alternatives. Clinical data in these limited cases have demonstrated that orally administered MAT2203 targets infected tissues, is safe and effectively eradicates IFIs in the most challenging cases. MAT2203 has successfully treated serious infections throughout the body, including bone, CNS, lung, sinus, bladder, and skin, highlighting the tissue-targeted nature of the Company's LNC platform delivery technology.

#### Government Grants for MAT2203 Development

• Matinas is pursuing non-dilutive funding for the development of MAT2203 in multiple IFIs from BARDA and ARPA-H. The Company believes MAT2203 is well positioned to receive funding due to its oral, well-tolerated and broad-spectrum profile, positive feedback from the FDA Type B meeting, clinical success in the Phase 2 EnACT trial in cryptococcal meningitis and results from the Compassionate Use Program. A potential BARDA and/or ARPA-H award could be sufficient to fund development of MAT2203 through to market approval for the targeted IFI indications, as well as support supply chain and commercial readiness.

#### **Platform Collaborations**

#### BioNTech

- In May 2023, results of an initial in vivo study of an oral mRNA delivery formulation, conducted in collaboration with BioNTech, did not demonstrate oral preclinical activity.
- This single study, conducted in healthy mice, involved oral administration of a unique, proprietary, non-LNC formulation of BioNTech-supplied reporter mRNA (firefly luciferase).
- This proprietary, phosphatidylserine-containing nano-formulation, distinct from traditional LNCs, was developed by Matinas to handle the physical complexity and biological fragility of mRNA and other large oligonucleotides.
- This formulation had successfully delivered mRNA in vitro in multiple cell lines and because of the timelines required under the BioNTech collaboration was brought forward for oral in vivo evaluation.
- Additional internal Matinas in vivo studies of similar non-LNC mRNA formulations showed
  activity when administered systemically (intramuscularly and intraperitoneally). In addition,
  these formulations have demonstrated a high degree of stability out to at least 17 weeks at 4°
  Celsius which compares favorably to lipid nanoparticles (LNPs).
- Matinas has filed numerous provisional patent applications based upon these novel, unique, phosphatidylserine-based formulations.
- The research collaboration between Matinas and BioNTech has been concluded.

#### National Resilience

- Following expiration of the exclusive agreement with BioNTech in April 2023, Matinas' collaborative research program with National Resilience was expanded to focus on in vitro and in vivo delivery of mRNA.
- Specifically, National Resilience and Matinas will collectively focus on reporter and therapeutic oligonucleotide delivery; both in vitro and in vivo, against reference LNPs. Initial data is expected in the third quarter of 2023.

#### **LNC Internal Pipeline Development**

#### Internal siRNA Program

Matinas is working toward the generation of in vitro data from an internal program for the delivery
of silencing RNA (siRNA) therapies utilizing its LNC platform technology. Initial formulation data
are expected in the third quarter of 2023. This program will continue with multiple in vivo
biodistribution and animal efficacy studies planned for the second half of 2023.

#### First Quarter Financial Results

Revenue for the first quarter of 2023 was \$1.1 million, which was generated from research collaborations with BioNTech and Genentech. There was no revenue reported for the first quarter of 2022.

Total costs and expenses for the first quarter of 2023 were \$6.7 million compared with \$7.7 million for the first quarter of 2022. The decrease was primarily attributable to lower manufacturing costs of clinical trial materials, partially offset by higher headcount.

The net loss for the first quarter of 2023 was \$5.5 million, or \$0.03 per share, compared with a net loss for the first quarter of 2022 of \$6.0 million, or \$0.03 per share.

Cash, cash equivalents and marketable securities as of March 31, 2023 were \$24.9 million compared with \$28.8 million as of December 31, 2022. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second half of 2024.

#### Conference Call and Webcast

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. To participate in the call, please dial 877-484-6065 (Toll-Free) or 201-689-8846 (Toll). The live webcast will be accessible on the <a href="Investors">Investors</a> section of the company's website and archived for 90 days.

#### About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology to maximize global clinical impact and patient access. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery for both small molecules and larger, more complex molecules such as siRNA, antisense oligonucleotides, and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral) positions Matinas' LNC technology potentially to become a preferred next-generation intracellular drug delivery platform.

In addition, Matinas has recently developed a non-LNC phosphatidylserine-based nanoparticle delivery technology that takes advantage of the same unique biological properties of phosphatidylserine that play a key role in more traditional LNCs, but with its own unique structural characteristics that allow the *in vitro* and *in vivo* delivery of larger oligonucleotides like mRNA, with several distinct potential advantages over lipid nanoparticle alternatives. For more information, please visit www.matinasbiopharma.com.

#### Forward-looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to our business activities, our strategy and plans, our collaboration with National Resilience, Inc., the potential of our LNC platform and PS-NP delivery technologies, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products or platform delivery technologies on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive

officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.

#### **Investor Contact:**

LHA Investor Relations Jody Cain <u>Jcain@lhai.com</u> 310-691-7100

[Financial Tables to Follow]

# Matinas BioPharma Holdings, Inc. Condensed Consolidated Balance Sheets (in thousands, except for share data)

		March 31, 2023 (Unaudited)		December 31, 2022 (Audited)	
ASSETS:	(0)	induited)		xuanta)	
Current assets:					
Cash and cash equivalents	\$	5,739	\$	6,830	
Marketable debt securities		19,118		21,933	
Restricted cash – security deposit		50		50	
Prepaid expenses and other current assets		3,299		5,719	
Total current assets		28,206		34,532	
Non-current assets:					
Leasehold improvements and equipment – net		1,998		2,091	
Operating lease right-of-use assets – net		3,480		3,613	
Finance lease right-of-use assets - net		25		30	
In-process research and development		3,017		3,017	
Goodwill		1,336		1,336	
Restricted cash – security deposit		200	_	200	
Total non-current assets		10,056		10,287	
Total assets	\$	38,262	S	44,819	
LIABILITIES AND STOCKHOLDERS' EQUITY:					
Current liabilities:					
Accounts payable	\$	516	\$	618	
Accrued expenses		791		3,099	
Operating lease liabilities – current		585		562	
Financing lease liabilities – current		4		7	
Total current liabilities		1,896		4,286	
Non-current liabilities:					
Deferred tax liability		341		341	
Operating lease liabilities - net of current portion		3,379		3,533	
Financing lease liabilities - net of current portion		21		22	
Total non-current liabilities		3,741		3,896	
Total liabilities		5,637		8,182	
Stockholders' equity:					
Common stock par value \$0.0001 per share, 500,000,000 shares authorized at March 31, 2023 and December 31, 2022; 217,264,526					
issued and outstanding as of March 31, 2023 and December 31, 2022		22		22	
Additional paid-in capital		191,342		190,070	
Accumulated deficit		(158,144)		(152,631)	
Accumulated other comprehensive loss		(595)		(824)	
· · · · · · · · · · · · · · · · · · ·	100	32,625		36,637	
Total stockholders' equity					

# Matinas BioPharma Holdings, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data) Unaudited

Three Months Ended

	March 31,			
		2023		2022
Revenue:				
Contract Revenue	\$	1,096	\$	12
Costs and Expenses:				
Research and development		3,970		4,978
General and administrative	_	2,712	_	2,744
Total costs and expenses	_	6,682		7,722
Loss from operations		(5,586)		(7,722)
Sale of New Jersey net operating loss & tax credits				1,734
Other income, net	_	73	_	10
Net loss	\$	(5,513)	\$	(5,978)
Net loss per share – basic and diluted	\$	(0.03)	\$	(0.03)
Weighted average common shares outstanding:				
Basic and diluted		217,264,526		216,644,783
Other comprehensive gain/(loss), net of tax				
Unrealized gain/(loss) on securities available-for-sale		229		(484)
Other comprehensive gain/(loss), net of tax	-	229		(484)
Comprehensive loss	\$	(5,284)	\$	(6,462)

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# **Corporate Presentation**

May 10, 2023

www.matinasbiopharma.com NYSE American: MTNB



This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.



# Matinas Has Developed Two Distinct Platforms for Delivering Therapeutic Cargo Phosphatidylserine and its Unique Properties Link Both Platforms



Lipid Nanocrystals™ (LNCs)



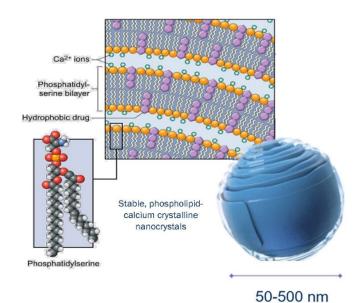


Phosphatidylserine Nanoparticles

Cargo	Small molecules     Small Oligos (ASOs/siRNA)	Large Oligos (mRNA, DNA)
Routes of Administration	Multiple (including oral)	Systemic (IM, IP)
Characteristics	50-1000 nm     Negative charge	<ul><li>100-200 nm</li><li>Positive charge</li></ul>
Components	Phosphatidylserine (PS)     Lipid conjugated small oligo or small molecule     Calcium	<ul> <li>Phosphatidylserine (PS)</li> <li>Lipoplex (mRNA + cationic lipid)</li> <li>Neutral lipids</li> </ul>
Cellular uptake (in vitro)	Somatic - Tumor (HeLa, melanoma), HEK     Immune - professional phagocytes, NK cells, T cells	<ul> <li>Somatic - Tumor (HeLa, melanoma), HEK</li> </ul>
In vivo delivery / efficacy	Small molecules - yes (oral)     Small oligos - yes (intranasal; oral TBD)	Large oligos (mRNA) – yes (IM and IP)
Key Features	Targeted oral, extrahepatic delivery PS acts as targeting ligand for professional pha PS also facilitates delivery to sites of infection, tumor Reduced toxicity, low immunogenicity	• Succeptul in vivo delivery of mPNA



### Lipid Nanocrystals (LNCs): A Clinically Validated Intracellular Delivery Platform



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#### Delivery of small molecules and small oligonuceotides

 Successful delivery of small molecules, proteins, nucleic acid polymers (siRNA, ASOs), and vaccines

#### **Extra-hepatic targeting**

- Selective uptake driven by phosphatidylserine enables delivery in infection, inflammation, oncology
- Validated Blood-Brain-Barrier penetration (MAT2203)

#### Oral delivery

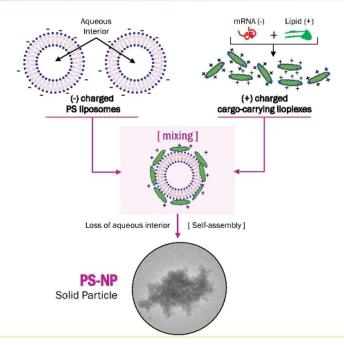
 Unique structure protects cargo in GI tract, avoids first-pass hepatic metabolism

#### Safe & stable

- Deliver high-target tissue concentrations of drug with low plasma levels and no absorption by non-target tissues
- No evidence of immunogenicity or cytotoxicity



### Phosphatidylserine Nanoparticles (PS-NPs): A New Delivery Option for mRNA



#### Specific Challenges with mRNA

- Large size
- Complex structure
- Negative charge
- · Fragility in biological systems
- Targeting
- · Safely delivering to cell interior
- · Toxicity, immunogenicity of delivery vehicle
- Stability of loaded delivery platform

#### Solution

- Neutralize negative charge with lipoplex
- Encapsulate lipoplex within PS-containing structure
- > Self-assemble to form anhydrous solid, stable particle

# Platforms are Clearly Differentiated from LNPs

	LNCs	LNPs	PS-NPs
Cargo	Small molecules Small Oligos	Small oligos Large Oligos	Large Oligos
Routes of Administration	Multiple (including oral)	Systemic	Systemic
Specific Delivery Target(s)	PS-driven Injured/infected tissues Professional Phagocytes Immune cells Tumors	Primarily liver	PS-driven (TBD)
Safety	Limit cargo toxicity Non-immunogenic	Can be cytotoxic Can elicit immune responses Anti-PEG antibodies can limit redosing	Low cytotoxicity in vitro
Manufacture	Simple, scalable Self-assembled	Multiple rounds of microfluidic mixing Nanoprecipitation of lipid particles	Simple, scalable Self-assembled
Stability	Highly stable even at room temperature	Cold chain requirements	mRNA formulations stable for at least 17 weeks at 4 °C
Targeting Ligands?	Possible	Challenging	Possible

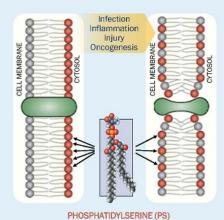
### Phosphatidylserine Enables Cellular Targeting and Facilitates Intracellular Delivery

**Targeting** 

#### Stressed Cells Externalize PS

Normally, PS is confined to the inner layer (facing cytosol)

With injury, PS moves from the inner layer to the outer layer of the cell membrane



With a wide variety of

### potential target cells

#### PROFESSIONAL PHAGOCYTES

- · Macrophages/monocytes
- Neutrophils
- Dendritic cells

#### NON-PROFESSIONAL PHAGOCYTES

· Fibroblasts, epithelial cells, endothelial cells

#### INJURED/STRESSED CELLS

- Infection
- Inflammation
- Other physiologic stressors

#### **TUMOR CELLS**

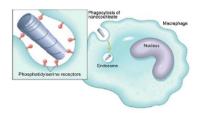
#### IMMUNE CELLS

- T-cells

OTHER ACTIVELY DIVIDING CELLS (including extracelluar pathogens)

# **PHAGOCYTOSIS**

PS on the outer layer of injured cells is an "eat-me" signal enabling recognition and uptake by professional phagocytes. Cargo-carrying LNCs/PS-NPs can be taken up in a similar fashion, with subsequent endosomal escape of cargo.



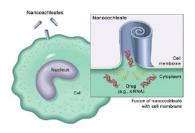
Delivery

PS-containing LNCs/PS-NPs potentially deliver their cargo

to the interior of cells by both phagocytosis and fusion

#### **FUSION**

PS on the outer cell membrane is also a precursor for direct membrane-to-membrane fusion and more rapid direct cytosolic delivery by cargocarrying LNCs/PS-NPs to cells expressing PS on their outer membranes.





# Internal and External Pipelines Extend Applications of LNCs and PS-NPs





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# **Addressing Emerging Threats From Fungal Infections**

The World Health Organization (WHO) released its first fungal priority pathogens list to guide research and development<sup>1</sup>





1:https://www.who.int/publications/i/ite m/9789240060241 Matinas is leveraging the safety and efficacy of MAT2203 to meet the needs of both critical and high priority groups identified by WHO

#### **CRITICAL PRIORITY**



Cryptococcal meningitis: Phase 2 success and QIDP



Aspergillosis: Preclinical data and QIDP

#### **HIGH PRIORITY**



Mucormycosis: Preclinical data



# MAT2203: A Novel Approach to Developing the Ideal Antifungal Agent

Innate Amphotericin B Characteristics	IV Amphotericin B Limitations	LNC Improvements
POTENT – broad-spectrum fungicidal	Only available through IV administration	Available systemically and orally (crosses BBB following oral administration)
Minimal drug-drug interactions	Significant toxicity and side effects	Well-tolerated and safe
Low propensity for resistance	High systemic exposure distributed throughout the body	Delivered directly into infected tissues
Active against susceptible and emerging drug-resistant fungal infections	Must be administered in hospital, increasing costs	Cost-effective with potential for significant health economic benefits

MAT2203 is a promising potential therapeutic option for the treatment of MULTIPLE serious and life-threatening fungal infections

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### Value Proposition for MAT2203

#### **ORAL ADMINISTRATION**

enables earlier release

from hospital or avoidance of home infusion



#### LACK OF NEPHROTOXICITY

enables longer treatment duration

supported by oral administration

#### LIFE CYCLE MANAGEMENT

Cryptococcal Meningitis (CM) (Proof of Concept)

VALUE

#### Invasive Fungal Infections (IFIs)

Aspergillosis, candidiasis, mucormycosis, endemic mycoses

Prophylaxis in Transplant Patients

#### Overall Development Strategy:

IFIs, supported by PoC in CM, focus on largest unmet medical need, resulting in significant commercial opportunity with streamlined 505(b)(2) development pathway with potential for prophylaxis indication

### **EnACT: Cohort 2 Results (Validation of Efficacy and Safety)**

#### **EnACT Clinical Data VALIDATES the Use of the LNC Platform** to Enable Oral Administration and Overcome Toxicity



endpoint threshold

- induction achieved **CSF** sterility
- No breakthrough Infections
- Survival at Day 30

MAT2203 was safe and well-tolerated over 6 weeks of treatment

 EFA for MAT2203 was 0.42 (95% CI 0.29 to

(primary endpoint threshold was 0.20)

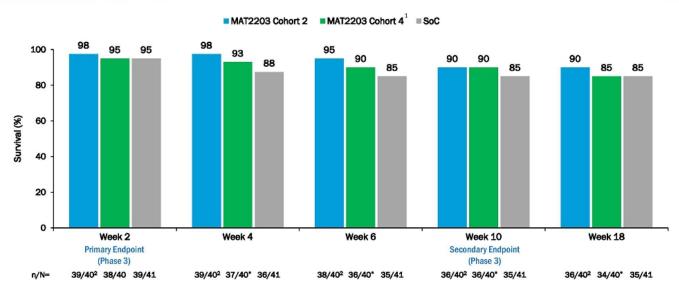
- 97% for patients receiving MAT2203
- 76% for patients receiving SOC
- · Over 10 weeks, patients showed no breakthrough infections post-MAT2203 treatment
- 98% for patients receiving MAT2203
- 88% for patients receiving IV Ampho (SOC)
- Repeat dosing showed no renal toxicity or electrolyte abnormalities
- No discontinuations due to AEs nor MAT2203-related

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# Cohort 2 and Cohort 4 Key Secondary Efficacy Endpoint: Survival



<sup>1.</sup> Combined SoC Cohorts 1 through 4.

Abbreviations: SoC=standard of care.

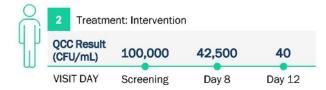


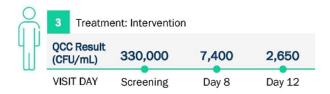
Patient 110554 died on Day 2 while on IV AMB and did not receive a full daily dose on MAT2203.
 Interim data, clinical data collection ongoing

# MAT2203 Cohort 4 Antifungal Activity

# Examples of Noteworthy Antifungal Activity in Patients with High Baseline Counts







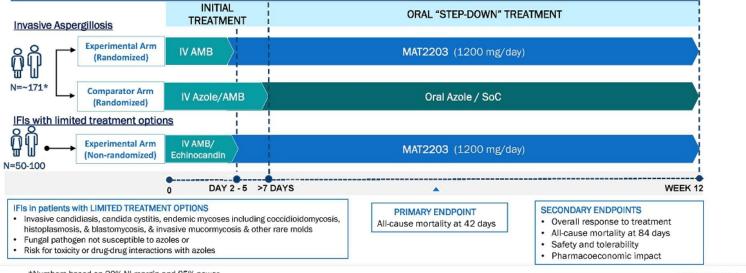
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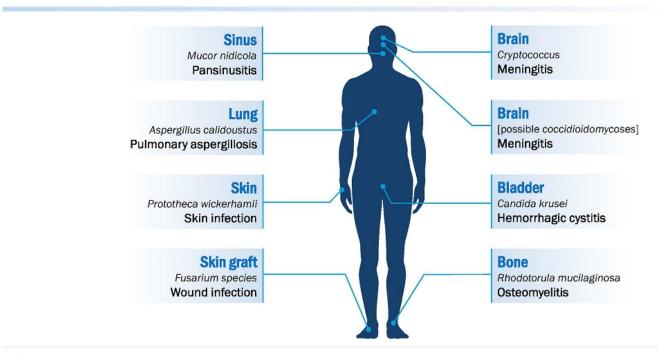
### Phase III Aspergillus/IFI Study - Preliminary Design (Subject to FDA Agreement)

- To assess the efficacy, safety, and tolerability of MAT2203 in patients with Invasive Aspergillosis; Patients will be randomized 2:1 to receive
  either oral MAT2203 as "step down" treatment after initial treatment with IV AMB (Experimental Arm) or Standard of Care (Comparator Arm)
- Non-randomized experimental arm: patients with serious, life-threatening IFIs with limited treatment options will receive oral MAT2203 as "step down" treatment after initial treatment with IV AMB (or an echinocandin)



\*Numbers based on 20% NI margin and 85% power

# MAT2203 Compassionate Use - Targeted Treatment of IFIs Throughout the Body



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# MAT2203 Compassionate Use Program

Patient Description	Reason for initiating MAT2203	Date started	Last visit	Comments
Patient #1 (37 v.o. female):  • Systemic lupus erythematosus, chronic non-healing ulcer on left foot with underlying osteomyelitis caused by Rhodotorula mucilanginosa.	<ul> <li>Patient had extensive surgical debridement and received AmBisome® with some improvement but developed severe electrolyte abnormalities which required hospitalization for monitoring and supplementation</li> </ul>			<ul> <li>Patient was at risk for amputation of her foot and unable to walk.</li> </ul>
				<ul> <li>Patient treated with IV L-AMB but developed serious renal toxicity; treatment had to be discontinued.</li> </ul>
		AUG 22	FEB 23	<ul> <li>After initiating treatment with oral MAT2203, renal function improved and remained at baseline throughout treatment</li> </ul>
				<ul> <li>Patient received 6 months of treatment with MAT2203 with complete clinical resolution and regaining full use of foot.</li> </ul>
Patient #2 (71 y.o. male):  • Chronic immunosuppression, multiple painful skin lesions on the right hand caused by Prototheca wickerhamii.	<ul> <li>Patient was treated with voriconazole and posaconazole for several months with inadequate response</li> </ul>	OCT 22	APR 23	Patient reported that skin lesions are much improved with less erythema and minimal if any pain; labs continue to be stable.
Patient #3 (15 y.o. female):  • AML, steroid-induced diabetes, with pansinusitis caused by Mucor nidicola, probable pulmonary aspergillosis caused by Aspergillus calidoustus	Patient had extensive surgical debridement of the sinuses with some improvement on IV AmBisome, but subsequently developed treatment-limiting renal toxicity.	DEC 22	APR 23	<ul> <li>Patient received 4 months of treatment with MAT2203 with condition improved.</li> <li>Sinus/brain MRI showed postsurgical changes without evidence of active infection.</li> <li>Chest CT showed two pulmonary nodules which are decreasing in size, with no new lesions.</li> <li>Renal function has returned to normal.</li> </ul>



# MAT2203 Compassionate Use Program

Patient Description	Reason for initiating MAT2203	Date started	Last visit	Comments
Patient #4 (39 y.o. male):  Crohn's disease, s/p colon resection with ileostomy, retroperitoneal abscess caused by azole-resistant Candida glabrata.	Patient did not tolerate IV Ambisome	DEC 22	JAN 23	Discontinued MAT2203 treatment after 2 days due to increased ileostomy output
Patient #5 (61 y.o. male):  Recurrent hemorrhagic cystitis due to chronic C krusei infection.	Developed worsening of renal function after treatment with IV amphotericin B	JAN 23	FEB 23	Complete clinical resolution after only 14 days of treatment with MAT2203, with negative urine culture     Renal function returned to normal
Patient #6 (40 y.o. female):  • C5-C6 quadriplegia with 34% TBSA burns and left foot dorsal wound yielding invasive Fusarium species; multiple skin and wound cultures positive for Fusarium.	Species resistant to voriconazole; Developed worsening of renal function after treatment with IV amphotericin B	APR 23	APR 23	Patient received 15 days of treatment with MAT2203 Renal function returned to normal Skin graft 90% healed Patient able to be transferred to another facility closer to home
Patient #7 (27 v.o. male):  • Recent BMT due to relapsed Hodgkin's; Proven invasive fungal meningitis; possible coccidioidomycosis	Failed voriconazole treatment; Patient did not tolerate IV Ambisome	May 23		Expected treatment duration of 6 months



# **Beyond Small Molecules:**

Efficient and Safe Delivery of Nucleic Acids Through LNCs and PS-NPs

Internal Pipeline Focus (siRNAs and ASOs)

and

External Collaborations (mRNA)



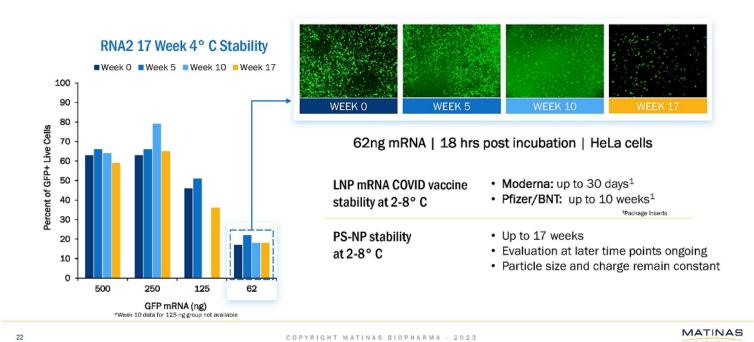
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# Unlocking the Full Potential of the LNC and PS-NP Platforms

Matinas is working internally and with third parties to broaden its pipeline of LNC and PS-NP-based therapeutics

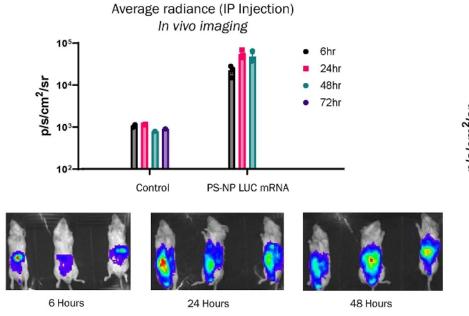
#### **FUTURE Potential Therapeutic Applications UNDER EVALUATION** INFECTION **IMMUNE RX PROVEN** Anti-infectives Vaccines Antivirals Immune tolerance Intracellular Delivery ONCOLOGY INFLAMMATION **Oral Formulations** Hematologic & solid Neuro-inflammatory of Nucleic Acids of Anti-Infectives tumor malignancies diseases siRNA mRNA Autoimmune diseases MAT2203 **FIBROSIS** ASO DNA Acute/chronic Organ fibrosis Inflammatory diseases · Wound healing **PULMONARY** Acute/chronic respiratory diseases

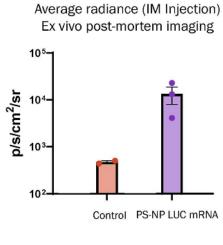
# PS-NP mRNA Formulations Remain Biologically Active for at Least 17 Weeks at 4°C



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# Successful In Vivo Delivery of Firefly Luciferase mRNA with PS-NPs





### National Resilience Collaboration Focused on mRNA and Nucleic Acids

# RESILIENCE

Focused on creating the processes and platforms that will allow scientists to make novel therapies quickly, safely, and at scale

### Provide manufacturing capabilities in:







Nucleic acids



Cell therapy

Potential benefits of collaboration

World-class manufacturing partner Leverage experience and know how with LNPs into accelerating PS-NP and potentially LNC maturation Access to leading technology companies around the world



# **Rapid Evolution of Platforms Sets Stage for Further Development**

Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023		
	Precise control of LNC	LNC uptake by LNC uptake by		Oral delivery of LNC small oligos in vivo		LNC uptake by LNC uptake by	oligos <i>in viv</i> o
	particle size	immune cells ex-vivo	immune cells in vitro	Delivery of small oligos to immune cells			
I BioN	Tech collaboration focused o	on <u>oral</u> mRNA delivery for vac	cines	Evaluate new partnerships for vaccines			
	Successful in-vitro delivery of mRNA	2 Log improvement in in vitro efficacy		Delivery of larger mRNA m	olecules		
			Demonstration of 17 week stability of PS- NP mRNA at 4°C	Additional extended stability	y work		
			In vivo delivery with PS-NP mRNA (IM/IP)	Optimization for systemic a	dministration (+ IV)		
				Ex-vivo delivery of large olig	os to immune cells		
				Addition of targeting ligano	ds		
				Evaluate partnerships for	therapeutic applications		

# **Expanding LNC and PS-NP Intellectual Property Portfolio**

### Continuingly increasing our patent suite to increase protection and exclusivity



MAT2203 potentially entitled to **12+ years of exclusivity** (QIDP & ODD status)



Global Platform IP base protection out to 2037 with 20 patents issued in last 5 years



Recent patent applications based on formulation work with large nucleic acids

# Strong IP & Regulatory Designations

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# **Experienced Leadership Team**

#### **EXECUTIVE TEAM**



Jerome D. Jabbour, J.D. Chief Executive Officer



James Ferguson, M.D.

Chief Medical Officer

AstraZeneca 2



Thomas Hoover, MBA Chief Business Officer





Theresa Matkovits, Ph.D. Chief Development Officer







Keith Kucinski, CPA, MBA Chief Financial Officer







Hui Liu, Ph.D., MBA Chief Technology Officer



#### **BOARD OF DIRECTORS**

Eric Ende, MD, MBA Chairman of the Board





**Herbert Conrad** Director





James Scibetta Director







Kathryn Corzo

Director







Natasha Giordano Director





Matthew Wikler, MD, MBA Director





Jerome D. Jabbour, J.D.



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# **Matinas Investment Thesis**

### **Financial Summary**



Runway into 2H 2024



\$24.9M1 in Cash. Cash Equivalents and Marketable Securities

1 as of 03/31/22

Non-Dilutive



**Financing Options** 

# 2023 Milestones & Catalysts



Q2 - FDA Meeting and Feedback on MAT2203 Phase 3 IFI program



Q3 - In vitro data from National Resilience Collaboration Q3 - In vitro data from internal ASO/siRNA program



2H - Potential MAT2203 Domestic/Global Partnership



2H - Potential BARDA/ARPA-H Grant for MAT2203/platform Development



2H - Potential additional platform collaborations



Q4 - In vivo Data from National Resilience Collaboration

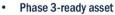


Q4 - In vivo efficacy study data from internal ASO/siRNA program



#### MAT2203





High unmet need



## **Substantial UPSIDE**

LNCs and PS-NPs Facilitating Delivery of Small Molecules and **Nucleic Acids** 

And

Establishing Internal and **External Pipelines**