
**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): August 15, 2022

FORTE BIOSCIENCES, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38052
(Commission
File Number)

26-1243872
(IRS Employer
Identification No.)

**3060 Pegasus Park Dr.
Building 6
Dallas, Texas**
(Address of Principal Executive Offices)

75247
(Zip Code)

Registrant's Telephone Number, Including Area Code: (310) 618-6994

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(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	FBRX	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 2.02. Results of Operations and Financial Condition.

On August 15, 2022, Forte Biosciences, Inc. (the “Company”) issued a press release reporting its financial results for the quarter ended June 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Current Report under Item 2.02 and the exhibit 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 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.

The Company has updated its corporate presentation that it uses when meeting with investors, analysts and others. A copy of the Company’s updated corporate presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated August 15, 2022
99.2	Corporate Presentation
104	The cover page of this Current Report on Form 8-K, formatted in inline XBRL

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.

Date: August 15, 2022

FORTE BIOSCIENCES, INC.

By: /s/ Antony Riley
Antony Riley
Chief Financial Officer

FORTE BIOSCIENCES, INC

FORTE BIOSCIENCES, INC. ANNOUNCES SECOND QUARTER 2022 RESULTS AND PROVIDES BUSINESS UPDATE

-Forte Biosciences is Developing a Novel Pipeline for the Treatment of Autoimmune Diseases-

-Leadership Strengthened with Appointments of Hubert Chen, M.D. as Chief Scientific Officer and Stephen Doberstein, Ph.D. to the Board of Directors-

-Ended second quarter 2022 with approximately \$38.5 million in cash and cash equivalents-

DALLAS, TX – AUGUST 15, 2022 – Forte Biosciences, Inc. (www.fortebiorx.com) (NASDAQ: FBRX), a biopharmaceutical company focused on autoimmune diseases, today announced second quarter 2022 results and provided a business update.

“Forte is excited to continue down our new path as we develop novel compounds for the treatment of autoimmune diseases, including potentially graft versus host disease (GvHD), vitiligo and alopecia areata which represent combined markets of over \$6 billion.” said Paul Wagner, Ph.D., President and Chief Executive Officer of Forte Biosciences. “We expect FB-102, our lead molecule, to be in the clinic late 2023 or early 2024. We believe that our innovative approach to treating autoimmune disease has the potential to drive significant value for Forte shareholders. Beyond FB-102 we will continue to strategically evaluate opportunities to create value for shareholders.”

Second Quarter 2022 Business Highlights

In May 2022, Forte appointed Steve Doberstein, Ph.D. to its board of directors, which further strengthened Forte’s board of directors. Dr. Doberstein previously served at the Chief Research and Development Officer at Nektar Therapeutics and has led research efforts at Xencor, FivePrime, Exelixis and Xoma.

In June 2022, Forte announced that Dr. Hubert Chen, M.D., joined the company as Chief Scientific Officer and President. Dr. Chen previously served as Chief Medical Officer at Metacrine, a clinical-stage company focused on the treatment of liver and gastrointestinal diseases. Prior, he was the Chief Scientific and Medical Officer of Pfenex, vice president of clinical development at Aileron Therapeutics, vice president of translational medicine at Regulus Therapeutics, and senior director of clinical research at Amylin Pharmaceuticals.

“Forte is tremendously fortunate that Steve and Hubert have agreed to join Forte. They are both thought leaders in the industry and will add significant experience and perspective to our pre-clinical and clinical development efforts.” said Dr. Wagner.

Forte ended the second quarter of 2022 with approximately \$38.5 million in cash and cash equivalents. Forte had approximately 14.8 million shares of common stock outstanding as of June 30, 2022. Subsequent to the June quarter-end, Forte issued an additional 5.6 million shares of common stock between July 1 and August 10, 2022 for gross proceeds of approximately \$7.0 million under its At-the-Market (ATM) financing facility further strengthening its balance sheet.

Second Quarter 2022 Operating Results

Research and development expenses were \$1.0 million and \$3.5 million for the three months ended June 30, 2022 and 2021, respectively. Research and development expenses were \$1.7 million and \$6.8 million for the six months ended June 30, 2022 and 2021, respectively. The decreases in 2022 were primarily due to the wind down of our FB-401 program as the Company began the shift in development activities to autoimmune indications with FB-102.

General and administrative expenses were \$2.0 million and \$2.2 million for the three months ended June 30, 2022 and 2021, respectively. The decrease in 2022 was primarily due to a decrease in legal and professional expenses partially offset by an increase in stock-based compensation and other expenses. General and administrative expenses were \$3.8 million and \$3.6 million for the six months ended June 30, 2022 and 2021, respectively. The increase in 2022 was primarily due to an increase in stock-based compensation expense partially offset by a decrease in legal and professional expenses.

Net loss per share were (\$0.21) and (\$0.43) for the three months ended June 30, 2022 and 2021, and (\$0.38) and (\$0.79) for the six months ended June 30, 2022 and 2021, respectively.

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	<u>June 30, 2022</u> (unaudited)	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,548	\$ 42,044
Prepaid expenses and other current assets	298	476
Total current assets	<u>38,846</u>	<u>42,520</u>
Other assets	874	786
Total assets	<u>\$ 39,720</u>	<u>\$ 43,306</u>
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 698	\$ 946
Accrued liabilities	815	812
Total current liabilities	<u>1,513</u>	<u>1,758</u>
Commitments and contingencies (Note 4)		
Series A Convertible Preferred Stock, \$0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of June 30, 2022 (unaudited) and December 31, 2021; aggregate liquidation preference of \$0 as of June 30, 2022 (unaudited) and December 31, 2021	—	—
Stockholders' equity		
Common stock, \$0.001 par value: 200,000,000 shares authorized as of June 30, 2022 (unaudited) and December 31, 2021; 14,761,261 and 14,754,447 shares issued and outstanding at June 30, 2022 (unaudited) and December 31, 2021, respectively	15	15
Additional paid-in capital	116,959	114,698
Accumulated deficit	<u>(78,767)</u>	<u>(73,165)</u>
Total stockholders' equity	<u>38,207</u>	<u>41,548</u>
Total liabilities, convertible preferred stock and stockholders' equity	<u>\$ 39,720</u>	<u>\$ 43,306</u>

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share amounts)

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 1,034	\$ 3,523	\$ 1,727	\$ 6,845
General and administrative	1,986	2,224	3,807	3,643
Total operating expenses	<u>3,020</u>	<u>5,747</u>	<u>5,534</u>	<u>10,488</u>
Loss from operations	(3,020)	(5,747)	(5,534)	(10,488)
Other expenses, net	(15)	(65)	(68)	(128)
Net loss	<u>\$ (3,035)</u>	<u>\$ (5,812)</u>	<u>\$ (5,602)</u>	<u>\$ (10,616)</u>
Per share information:				
Net loss per share - basic and diluted	\$ (0.21)	\$ (0.43)	\$ (0.38)	\$ (0.79)
Weighted average shares outstanding, basic and diluted	14,761,261	13,603,181	14,760,538	13,429,018

Additional detail on our financial results for the second quarter of 2022 can be found in Forte's Form 10-Q as filed with the SEC on August 15, 2022. You can also find more information in the investor relations section of our website at www.fortebiorx.com.

About Forte

Forte Biosciences, Inc. is a biopharmaceutical company focused on autoimmune diseases. Forte's lead product, FB-102, is a proprietary molecule with potentially broad autoimmune applications.

Forward Looking Statements

Forte cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the Company's current beliefs and expectations. Forward looking statements include statements regarding Forte's beliefs, goals, intentions and expectations regarding its product candidates. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Forte's ability to obtain sufficient additional capital to continue to advance Forte's product candidates and preclinical programs; Results from early-preclinical studies may not be predictive of results from later-stage studies or clinical trials; uncertainties associated with the clinical development and regulatory approval of Forte's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates; risks associated with the failure to realize any value from product candidates and preclinical programs

being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and risks related to the impact of the COVID-19 outbreak on Forte's operations, the biotechnology industry and the economy generally. Information on these and additional risks, uncertainties, and other information affecting Forte's business and operating results is contained in Forte's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 as filed with the Securities and Exchange Commission on August 15, 2022 and in its other filings with the Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Forte undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Contact:

LifeSci Advisors

Mike Moyer, Managing Director

mmoyer@lifesciadvisors.com

FORTE BIOSCIENCES

DEVELOPING TREATMENTS FOR AUTOIMMUNE DISEASES

CORPORATE PRESENTATION

AUGUST 2022

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

- Certain statements contained in this presentation regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Act of 1995, known as the PSLRA. These include statements regarding management's intention, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Forte Biosciences, Inc. ("we", the "Company" or "Forte") undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as "anticipates," "believes," "plans," "expects," "projects," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.
- Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to the sufficiency of the Company's cash balance to fund the Company's activities, and the expectation with respect thereto; the business and prospects of the Company; Forte's plans to develop and potentially commercialize its product candidates, including FB-102; Results from early-preclinical studies may not be predictive of results from later-stage studies or clinical trials; the timing of initiation of Forte's planned clinical trials; the timing of the availability of data from Forte's clinical trials; the timing of any planned investigational new drug application or new drug application; Forte's plans to research, develop and commercialize its current and future product candidates; Forte's ability to successfully enter into collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Forte's product candidates; Forte's commercialization, marketing and manufacturing capabilities and strategy; Forte's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Forte's competitors and its industry; the impact of government laws and regulations; Forte's ability to protect its intellectual property position; Forte's estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction; and the impact of COVID-19 on the Company, the Company's industry or the economy generally.
- The known risks and uncertainties are described in detail under the caption "Risk Factors" and elsewhere in the Company's Annual Report on Form 10-K for the year ending December 31, 2021 and subsequent filings with the Securities and Exchange Commission. Forward-looking statements included in this presentation are based on information available to Forte as of the date of this presentation. Accordingly, our actual results may materially differ from our current expectations, estimates and projections. Forte undertakes no obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation.

SUMMARY OF FORTE BIOSCIENCES: POTENTIAL FIRST-IN-CLASS BIOTHERAPEUTIC FOR THE TREATMENT OF AUTOIMMUNE DISEASES

Examples of large market with unmet need

- **Graft-vs-Host-Disease (GvHD)/Transplant Rejection**
 - Chronic GvHD is on the rise with the increased use of allogeneic hematopoietic stem cell transplantation (HSCT)
 - It is estimated that 10-15% of tissue transplants are rejected, and US 33,000 tissues transplants were performed in the US in 2020
 - The global GvHD treatment market size was estimated at \$1.6 billion in 2021 and is projected to reach \$2.8 billion by 2027 ⁽²⁾
- **Vitiligo**
 - It is estimated that vitiligo affects 2 million people in the US (NIH)
 - The global vitiligo treatment market size was estimated at \$1.2 billion in 2018 and is projected to reach \$1.9 billion by 2026 ⁽³⁾
- **Alopecia Areata (AA)**
 - It is estimated that alopecia areata affects 700,000 people in the US with moderate to severe at 300,000 people (NIH)
 - The global alopecia treatment market size was estimated at \$2.7 billion in 2020 and is projected to reach \$4.9 billion by 2028 ⁽¹⁾
- While JAK inhibitors have demonstrated efficacy in AA, GvHD and vitiligo, black box warnings have dampened enthusiasm for JAK inhibitors. As a result, there remains a significant unmet need for safe and effective therapies
- FB-102 has potentially other autoimmune applications including celiac disease, eosinophilic esophagitis and Type 1 diabetes
- Forte expects FB-102 to be in the clinic in late 2023/early 2024

Financing / Management

- Management team with significant drug development, innovation and corporate strategy experience
- Board with significant drug development, clinical and commercial experience
- Cash Balance as of June 30, 2022 was \$38.5M.

FORTE BIOSCIENCES: OVERVIEW OF FB-102

- **Therapeutic Molecule**
 - Antagonism of pathway for autoimmune disease
 - Proprietary molecule
- **Multibillion dollar revenue potential**
 - Preclinical PoC validates target
 - Significant unmet need in autoimmune diseases including potentially graft-vs-host disease / transplant rejection, vitiligo and alopecia areata
 - Potential for durable responses (infrequent dosing = improved uptake and compliance)
 - Broad indication expansion opportunities

EXPERIENCED MANAGEMENT

- Forte's management has extensive experience in manufacturing, quality, and regulatory and clinical development in autoimmune disorders

Paul Wagner, PhD, CFA – CEO					LEHMAN BROTHERS
Hubert Chen, MD – Chief Scientific Officer					
Tony Riley, CPA – Chief Financial Officer					
Chris Roenfeldt – Chief Operating Officer					
Steven Ruhl – Chief Technical Officer					

EXPERIENCED SCIENTIFIC ADVISORY BOARD

Scientific Advisory Board (SAB)

- Steve Doberstein, PhD – Former Head of Research and Development at Nektar Therapeutics
- Prof. Lawrence Eichenfield, MD – Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, Editor in Chief of Pediatric Dermatology
- Dr. Barbara Finck, MD – Former CMO of Coherus BioSciences
- Prof. Eric Simpson, MD – Professor of Dermatology, Oregon Health & Science University, Portland
- Dr. Patricia Walker, MD, PhD – Former CMO of Allergan Medical and Dermatology TA Head

BOARD WITH EXTENSIVE PUBLIC COMPANY EXPERIENCE

- Board with strong track record at public companies
 - Steve Doberstein, PhD – Former Head of Research and Development at Nektar Therapeutics
 - Prof. Lawrence Eichenfield, MD – Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, Editor in Chief of Pediatric Dermatology
 - Barbara Finck, MD – Former CMO of Coherus BioSciences
 - Steve Kornfeld, CFA – Founder and Partner of Castle Peak Partners, Former portfolio manager at Franklin Templeton Investments & Franklin Biotech Discovery Fund
 - Paul Wagner, PhD, CFA – Founder and CEO of Forte Biosciences
 - Dr. Patricia Walker, MD, PhD – Former CMO of Allergan Medical and Dermatology TA Head
 - Donald Williams – Former Partner at Grant Thornton and Ernst & Young

GRAFT-VS-HOST-DISEASE/TRANSPLANT REJECTION OVERVIEW

- Graft-versus-host disease (GvHD) is a common potentially life-threatening complication associated with allogeneic hematopoietic stem cell transplantation (HSCT) in which the transplanted cells initiate an immune response against the transplant recipient:
 - Chronic GvHD prevalence and severity has increased in recent decades as the use of HSCT has increased ⁽¹⁾
 - 30% to 70% of patients who undergo allogeneic HSCT experience chronic GvHD ⁽²⁾
- Transplant Rejection occurs when the immune system of the transplant recipient rejects the transplanted tissue:
 - 33,000 tissue transplants from deceased donors in the US in 2020 ⁽³⁾
 - Rejection of the transplanted tissues occur in 10-15% of all transplants ⁽⁴⁾

1) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4304105/#:~:text=Management%20of%20chronic%20GVHD%20has,or%20without%20cyclosporine%20or%20tacrolimus.>

2) <https://www.healio.com/news/hematology-oncology/20201204/ruxolitinib-effective-as-second-line-therapy-for-chronic-gvhd>

3) <https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/#:~:text=As%20a%20result%20of%20the,of%2039%2C719%20set%20in%202019.>

4) <https://www.donoralliance.org/newsroom/donation-essentials/preventing-organ-and-tissue-rejection/#:~:text=However%2C%20new%20medications%20are%20continually,rejection%20of%20tissue%20is%20uncommon.>

VITILIGO OVERVIEW



- Vitiligo is characterized by the loss of melanocytes which are cells that produce skin pigmentation
- Vitiligo results in discolored patches appearing in the skin, hair and mucous membrane
- Vitiligo is an autoimmune disease in which the immune system attack melanocytes
- It is estimated that 2M people in the US⁽¹⁾ have vitiligo with world-wide prevalence at 0.5% to 2% the population⁽²⁾
- Current treatments include black box warnings
- There remains a significant unmet need for safe and effective therapies for treating vitiligo

CONFIDENTIAL

1) <https://jamanetwork.com/journals/jamadermatology/fullarticle/2785895#:~:text=Conclusions%20and%20Relevance%20Results%20of%202.8%20million%20cases%20in%202020>

2) <https://pubmed.ncbi.nlm.nih.gov/22458952/#:~:text=The%20prevalence%20of%20vitiligo%20ranges,ranges%20between%200.5%20and%202%25>

ALOPECIA AREATA OVERVIEW



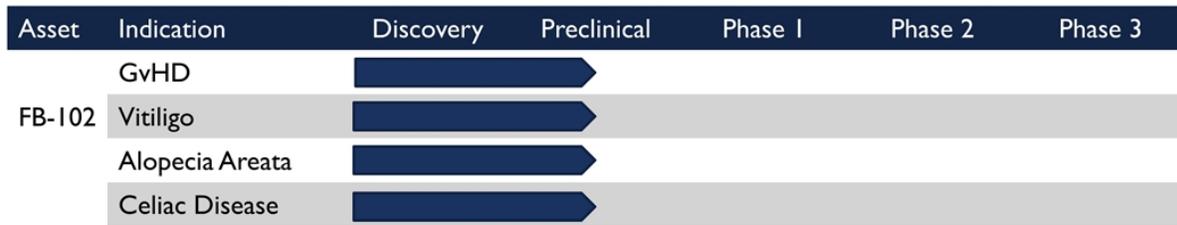
- Alopecia Areata (AA) is characterized by nonscarring hair loss generally on the scalp but can also affect other areas of the body
- AA is an autoimmune disease in which immune cells attack and damage hair follicles
- There remains a significant unmet need for safe and effective therapies for AA
- In the US, the prevalence of AA is estimated at 700,000 ⁽¹⁾ people with worldwide prevalence at 0.5% to 2% of the population⁽²⁾
 - Most individuals experience the onset of AA by the age of 40 and nearly half experience the onset by age 20
 - Alopecia areata can affect males and females at any age and the lifetime risk of experience 1–2%

1) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7131990/#:~:text=Conclusion,0.09%25%20\(300%2C000%20persons\).](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7131990/#:~:text=Conclusion,0.09%25%20(300%2C000%20persons).)
2) <https://pubmed.ncbi.nlm.nih.gov/22458952/#:~:text=The%20prevalence%20of%20vitiigo%20ranges,range%20between%200.5%20and%202%25>

FB-102 HAS POTENTIAL IN SEVERAL OTHER AUTOIMMUNE DISEASES

- Eosinophilic esophagitis
- Atopic Dermatitis
- Celiac Disease
- Type I Diabetes
- Ulcerative colitis
- Non-Alcoholic Steatohepatitis (NASH)

PIPELINE



- Forte expects FB-102 to be in the clinic in the late 2023/early 2024

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Examples of large market with unmet need

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