# 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): March 1, 2022**

# SYNDAX PHARMACEUTICALS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-37708** | **32-0162505** |
|---|---|---|
| **(state or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| | |
|---|---|
| **Building D, Floor 3**<br>**35 Gatehouse Drive**<br>**Waltham, Massachusetts**<br>**(Address of principal executive offices)** | **02451**<br>**(Zip Code)** |

**Registrant's telephone number, including area code: (781) 419-1400**

**(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 or to be 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 | SNDX | 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 March 1, 2022, Syndax Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing its financial results for the quarter and year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and 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 it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended (the "***Securities Act***"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensation Arrangements of Certain Officers.**

On March 1, 2022, the Company issued a press release announcing that Kate Madigan, M.D. will join the Company as Chief Medical Officer, effective March 1, 2022. Also on March 1, 2022, Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of the Company, notified the Company of his intention to retire and resign from his position as Chief Medical Officer. The notice was given in connection with a succession plan developed by Dr. Meyers and the Company. Dr. Meyers will continue with the Company through June 2022 before transitioning to serve in a consulting capacity.

Prior to joining the Company, Dr. Madigan served as Vice President, Head of Clinical Development at Syros Pharmaceuticals. Prior to joining Syros, she served as Senior Medical Director at Alnylam Pharmaceuticals, and was a Medical Director in Biogen's Rare Disease Innovation Unit. Dr. Madigan previously held various academic positions of increasing responsibility at University of California San Diego/ Rady Children's Hospital-San Diego. Dr. Madigan received a B.A. in Asian Studies from Dartmouth College and an M.D. from the Keck School of Medicine of the University of Southern California.

There are no arrangements or understandings with the Company pursuant to which Dr. Madigan was appointed to serve as Chief Medical Officer. There are no family relationships between Dr. Madigan and any director or executive officer of the Company, and there are no related party transactions of the kind described in Item 404(a) of Regulation S-K in which Dr. Madigan was a participant.

In connection with her appointment, the Company entered into an employment agreement with Dr. Madigan, effective March 1, 2022 (the "***Employment Agreement***"), providing for the terms of her employment, including (i) an annual base salary of $440,000; (ii) an annual target bonus equal to 40% of her base salary, which bonus will be pro-rated for 2022; and (iii) an inducement stock option award to purchase 180,000 shares of the Company's common stock, exercisable at a price per share equal to the closing price of the Company's common stock on the Nasdaq Global Select Market on March 1, 2022, the date of grant. Twenty-five percent (25%) of the shares subject to such option shall vest on the one-year anniversary of the vesting commencement date, and one forty-eighth (1/48th) of the shares of common stock subject to such option shall vest monthly thereafter on the last day of each month over the following thirty-six (36) months until all of the shares subject to such option are fully vested, subject to continued service. In addition to the annual target bonus, Dr. Madigan will receive a one-time sign-on bonus of $135,000. In the event of Dr. Madigan's voluntary resignation within two years of March 1, 2022, she will repay a prorated portion of such sign-on bonus to the Company promptly following the termination of employment.

Dr. Madigan's employment agreement further provides that in the event her employment is terminated without "cause," as defined in his employment agreement, or she terminates her employment for "good reason," as defined in her employment agreement, she is entitled to (i) a lump sum severance payment equal to nine months base salary, (ii) payment on his behalf of up to nine months of health insurance benefits continuation and (iii) with respect to equity awards granted to Dr. Madigan prior to the date of her termination, accelerated vesting and the lapse of any reacquisition or repurchase rights that the Company holds with respect to such equity awards for the portion of such equity awards that would have otherwise vested within the 12-month period following the date of Dr. Madigan's termination were she to remain employed with the Company during such 12-month period. If Dr. Madigan's employment is terminated without cause or she terminates her employment for good reason within three months prior to, or 12 months after, a "change in control" of the Company, as defined in her employment agreement, she is instead entitled to (a) a lump sum severance payment equal to the sum of 12 months base salary and 100% of the greater of (1) the average annual target performance bonus paid to her for the preceding three years or (2) her annual target performance bonus in effect as of the change in control, (b) payment on her behalf of up to 12 months of health insurance benefits continuation and (c) full accelerated vesting on all of her unvested options and the lapse of any reacquisition or repurchase rights that the Company holds with respect to any other equity award granted to her pursuant to any of the Company's equity incentive plans. In order to receive her severance benefits, Dr. Madigan must sign a general release of claims.

Dr. Madigan's employment agreement further provides that in the event the severance and other benefits provided for or otherwise payable to her constitute "parachute payments" within the meaning of Section 280G of the Code and are subject to the excise tax imposed by Section 4999 of the Code, the Company will pay either (i) Dr. Madigan's severance benefits under the employment agreement in full or (ii) only a part of Dr. Madigan's severance benefits under the employment agreement such that Dr. Madigan receives the largest

payment possible without the imposition of the excise tax, in each case, depending upon which alternative would result in Dr. Madigan receiving the greater net after-tax payment.

In connection with her appointment as Chief Medical Officer, Dr. Madigan entered into the Company's standard form of Indemnification Agreement, a copy of which was filed as Exhibit 10.21 to the Registration Statement on Form S-1 (File No. 333-208861) filed with the SEC on January 4, 2016.

The foregoing description of the Employment Agreement does not purport to be complete and is qualified in its entirety by the full text of the Employment Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2022. A copy of the Company's press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 7.01. Regulation FD Disclosure.**

A copy of the Company's press releases announcing the foregoing are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2. The information in this Item 7.01 and in Exhibit 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference to such filing.

**Item 9.01. Financial Statements and Exhibits.**
(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated March 1, 2022 |
| 99.2 | Press Release, dated March 1, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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.

**SYNDAX PHARMACEUTICALS, INC.**

By: /s/ Michael A. Metzger
Michael A. Metzger
Chief Executive Officer

Dated: March 1, 2022

**Syndax Pharmaceuticals Reports Fourth Quarter 2021 Financial Results and Provides Clinical and Business Update**

*- Enrollment remains on track for pivotal programs of SNDX-5613 and axatilimab; topline data expected starting in the first half of 2023 -*

*- Initiation of three new trials of SNDX-5613 in NPM1 and MLLr acute leukemias, including in the first-line and maintenance settings, expected in 1H22 -*

*- Company to host conference call today at 4:30 p.m. ET -*

WALTHAM, Mass., March 1, 2022 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the fourth quarter ended December 31, 2021. In addition, the Company provided a clinical and business update.

"2021 was marked by substantial progress advancing our pipeline of novel cancer therapies, including the initiation of our two pivotal programs for which we expect to report topline data starting in the first half of 2023," said Michael A. Metzger, Chief Executive Officer. "We believe SNDX-5613 is poised to serve as a first-to-market and best-in-class menin inhibitor for patients with genetically defined acute leukemias. With our first regulatory filing for SNDX-5613 expected in 2023, we are keenly focused on laying the groundwork for the potential commercial launch, while concurrently expanding into the frontline and maintenance settings, with three new trials expected to begin in the first half of this year."

Mr. Metzger continued, "Enrollment remains on track in our global pivotal Phase 2 AGAVE-201 trial of axatilimab in chronic graft-versus-host disease (cGVHD), with topline data expected in the first half of 2023 and a potential Biologic License Application (BLA) filing in 2023. Beyond cGVHD, we are also working to unlock axatilimab's full potential in additional fibrotic diseases where the monocyte-macrophage lineage plays a vital role, with commencement of a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) expected in the fourth quarter of this year."

**Recent Pipeline Progress and Anticipated Milestones**

*SNDX-5613*

- During an oral presentation at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021, the Company reported positive data demonstrating continued robust clinical activity with durable responses in the Phase 1 portion of the AUGMENT-101 trial of SNDX-5613, the Company's highly selective oral menin inhibitor, in relapsed/refractory (R/R) patients with mutant nucleophosmin (NPM1) or mixed lineage leukemia rearranged (MLLr) acute leukemias.
- The pivotal Phase 2 portion of AUGMENT-101 is ongoing and the Company expects to complete enrollment in at least one of the three pivotal cohorts later this year. The trials are expected to enroll a total of 64 adult and up to 10 pediatric patients across each of three distinct trial populations: patients with NPM1 mutant acute myeloid leukemia (AML), patients with MLLr AML, and patients with MLLr acute lymphocytic leukemia (ALL). Based on discussions with the U.S. Food and Drug Administration (FDA), AUGMENT-101 may serve as the basis for regulatory filings in each of the three distinct populations. The Company expects to receive initial topline data from the trials starting in the first half of 2023, with the potential for the first NDA filing in 2023.
- In December 2021, the Company announced that the European Commission granted Orphan Drug Designation (ODD) to SNDX-5613 for the treatment of AML. SNDX-5613 was previously granted ODD for the treatment of adult and pediatric AML by the U.S. FDA.

- The Company expects to initiate three additional trials in the first half of 2022 to assess the safety, tolerability, and preliminary anti-leukemic efficacy of SNDX-5613 in combination with venetoclax and azacitidine as part of the Leukemia & Lymphoma Society's Beat® AML Master Clinical Trial, in combination with chemotherapy in patients with R/R NPM1 or MLLr acute leukemias in the AUGMENT-102 trial, and in NPM1 or MLLr patients with measurable residual disease progression following initial treatment as part of the Australian Leukemia and Lymphoma Group (ALLG) INTERCEPT Master Clinical Trial.

*Axatilamab*

- In December 2021, the Company reported updated positive data demonstrating broad activity and tolerability of axatilimab, its anti-CSF-1R monoclonal antibody, in a Phase 1/2 trial in patients with cGVHD. The data were presented during an oral session at the 63rd ASH Annual Meeting.

- Enrollment is ongoing in the Company's global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD, with topline data expected in the first half of 2023. The trial is evaluating the safety and efficacy of three doses and schedules of axatilimab. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for cGVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score. Topline data from the trial are expected in the first half of 2023, with the potential for a BLA filing in 2023.
- In December 2021, Syndax and Incyte closed its previously announced exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab. Closing of the agreement triggered a $117 million upfront payment by Incyte to Syndax, as well as Incyte's $35 million equity investment in Syndax.

*Corporate Updates*

- Earlier today, the Company announced the appointment of Kate Madigan, M.D., as Chief Medical Officer. Dr. Madigan brings to Syndax over 20 years of clinical hematology expertise and broad experience in the design and execution of early to late-stage clinical programs across oncology and rare diseases.

- In February 2022, the Company announced the transition of Michael A. Metzger to the role of Chief Executive Officer and Briggs W. Morrison, M.D., to President, Head of Research and Development. Mr. Metzger and Dr. Morrison, who both serve on the Company's Board of Directors, joined Syndax together in 2015.

**Fourth Quarter 2021 Financial Results**

As of December 31, 2021, Syndax had cash, cash equivalents and short-term investments of $439.9 million and 59.0 million shares and share equivalents issued and outstanding. This includes 4.0 million pre-funded warrants.

Fourth quarter 2021 research and development expenses increased to $23.9 million from $15.5 million, and for the full year increased to $88.2 million compared to $50.4 million for 2020. The fourth quarter and full year increases were primarily due to increased clinical trial and CMC activities.

General and administrative expenses for the fourth quarter 2021 increased to $6.9 million from $4.7 million, and, for the year ended December 31, 2021, increased to $25.2 million compared to $22.5 million for the prior year. The fourth quarter and full year increases were primarily due to increased professional fees and employee related expenses.

License revenue for the fourth quarter 2021 increased to $126.6 million from $0.4 million, and, for the year ended December 31, 2021, increased to $139.7 million compared to $1.5 million for the prior year due to revenue related to the license and collaboration agreement with Incyte and the termination of the Company's license agreement with KKC.

For the three months ended December 31, 2021, Syndax reported a net profit attributable to common stockholders of $96.2 million or $1.81 per share compared to a net loss attributable to common stockholder of $20.4 million or $0.44 per share for the prior year period. For the year ended December 31, 2021, Syndax reported a net profit attributable to common stockholders of $24.9 million or $0.48 per share, compared to a net loss attributable to common stockholders of $77.8 million or $1.87 per share for the prior year.

**Financial Update and Guidance**

In December 2021, Syndax issued 4,945,000 shares of its common stock and pre-funded warrants to purchase shares of its common stock at approximately $17.50 per share. As a result, Syndax received gross proceeds of approximately $86.5 million. Syndax also issued 1,421,523 shares of its common stock in connection with the Share Purchase Agreement with Incyte Pharmaceuticals at a 30% premium to market for proceeds of $35.0 million.

For the first quarter of 2022, research and development expenses are expected to be $30 to $35 million, and total operating expenses are expected to be $38 to $42 million. For the full year of 2022, research and development expenses are expected to be $130 to $140 million, and total operating expenses are expected to be $160 to $170 million. This does not include any potential cost offsets due to the Incyte collaboration.

**Conference Call and Webcast**

In connection with the earnings release, Syndax's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Tuesday, March 1, 2022.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 4019975
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/pqahpntn

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of the Company's website, www.syndax.com.

**About Syndax Pharmaceuticals, Inc.**

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's pipeline includes SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

**Syndax's Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials, the reporting of clinical data for Syndax's product candidates, the potential use of our product candidates to treat various cancer indications and fibrotic diseases, Syndax's fourth quarter and full-year 2021 net cash used in research and development and total operating activities, and first quarter and full year 2022 operating expense and cash guidance.. Many factors may cause differences between current expectations and actual results, including: unexpected safety or efficacy data observed during preclinical or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; failure of Syndax's collaborators to support or advance collaborations or product candidates; and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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**SYNDAX PHARMACEUTICALS, INC.**
**(unaudited)**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

| (In thousands) | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 439,936 | $ 293,065 |
| Total assets | $ 449,657 | $ 300,613 |
| Total liabilities | $ 41,289 | $ 48,425 |
| Total stockholders' equity (deficit) | $ 408,368 | $ 252,188 |
| | | |
| Common stock outstanding | 54,983,105 | 47,881,223 |
| Common stock and common stock equivalents* | 66,011,976 | 57,836,910 |
| | | |
| *Common stock and common stock equivalents: | | |
| Common stock | 54,983,105 | 47,881,223 |
| Options to purchase common stock | 6,921,514 | 6,379,235 |
| Restricted Stock Units | 132,333 | 18,500 |
| Pre-funded warrants | 3,975,024 | 3,557,952 |
| | 66,011,976 | 57,836,910 |

**SYNDAX PHARMACEUTICALS, INC.**
**(unaudited)**
## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| (In thousands, except share and per share data) | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| License fee revenue | $ 126,576 | $ 380 | $ 139,709 | $ 1,517 |
| Operating expenses: | | | | |
| Research and development | 23,900 | 15,522 | 88,248 | 50,435 |
| General and administrative | 6,927 | 4,718 | 25,241 | 22,505 |
| Total operating expenses | 30,827 | 20,240 | 113,489 | 72,940 |
| Loss from operations | 95,749 | (19,860) | 26,220 | (71,423) |
| Other income (expense), net | 449 | (563) | (1,294) | (1,735) |
| Net income (loss) | $ 96,198 | $ (20,423) | $ 24,926 | $ (73,158) |
| | | | | |
| Net income (loss) attributable to common stockholders | $ 96,198 | $ (20,423) | $ 24,926 | $ (77,064) |
| | | | | |
| Net income (loss) per share attributable to common stockholders--basic | $ 1.81 | $ (0.44) | $ 0.48 | $ (1.87) |
| | | | | |
| Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic | 53,176,334 | 46,054,850 | 52,064,809 | 41,308,242 |

Syndax

## Syndax Pharmaceuticals Announces Appointment of Kate Madigan, M.D., as Chief Medical Officer

WALTHAM, Mass., March 1, 2022 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced the appointment of Kate Madigan, M.D., to the role of Chief Medical Officer, effective immediately. Dr. Madigan, who brings to Syndax over 20 years of clinical hematology expertise and broad experience in the design and execution of early to late-stage clinical programs across oncology and rare diseases, will lead the Company's clinical development strategy. She will succeed Michael Meyers, M.D., Ph.D., who will continue with the Company through June before transitioning to serve in a consulting capacity.

"Dr. Madigan has a proven track record of driving the design and execution of late-stage clinical programs," said Briggs W. Morrison, M.D., President, Head of Research and Development at Syndax. "Her demonstrated acumen in oncology development in both the academic and industry settings will be invaluable as we continue to expand our pipeline. Her appointment is the result of a thorough succession planning process as we lay the groundwork for our evolution into a fully-integrated oncology company. I would like to thank Dr. Meyers for his dedication to Syndax over the years, having played an essential role in advancing both SNDX-5613 and axatilimab from Investigational New Drug filing to the pivotal stage. We look forward to his continued contributions as we work to bring innovative cancer therapies to patients in areas of high unmet need."

"With two ongoing pivotal programs for two first-in-class and potentially best-in-class medicines and subsequent U.S. Food and Drug Administration filings expected next year, Syndax is well positioned to make a meaningful impact in the treatment of some of the most underserved therapeutic areas," said Dr. Madigan. "The talented team at Syndax has already made impressive progress advancing the pipeline, and I look forward to building on that momentum to further advance the mission of realizing a future in which people with cancer live longer and better than ever before."

Dr. Madigan most recently served as Vice President, Head of Clinical Development at Syros Pharmaceuticals, where she oversaw the development and execution of clinical strategy across multiple solid and hematologic tumor programs. Prior to joining Syros, she served as Senior Medical Director at Alnylam Pharmaceuticals, and was a Medical Director in Biogen's Rare Disease Innovation Unit. Before moving into industry, Dr. Madigan held various academic positions of increasing responsibility at University of California San Diego/ Rady Children's Hospital San

Diego. Dr. Madigan received a B.A. in Asian Studies from Dartmouth College and an M.D. from the Keck School of Medicine of the University of Southern California.

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SNDX-G