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Finance Watch: Have Biopharma IPOs Hit Their Limit?

by Mandy Jackson

Public Company Edition: Three companies postponed or withdrew their offerings, but drug developers continue to pursue IPOs. Also, Biocon, BMS and Epizyme raised money through new debt, Five Prime capitalized on positive data and Synthetic Biologic engaged a strategic advisor.

Three biopharma firms were scheduled to launch initial public offerings during the week of 9-13 November but all three postponed or delayed their offerings, raising the question of whether the booming IPO market of 2020 finally has reached its limit. However, companies continue to join the IPO queue, suggesting there is still a market for some drug developers.

IN8bio, Inc. and *Inhibikase Therapeutics, Inc.* postponed their offerings and *Compass Therapeutics Inc.* withdrew its IPO plans on 13 November. Compass cited "market conditions" even though the Nasdaq is up more than 32% year to date and the Nasdaq Biotechnology Index (NBI) is up almost 17% so far in 2020.

All three planned IPOs were smaller offerings relative to most other biopharma IPOs that launched this year and stock performance generally has been worse for companies with smaller offerings. The average size of the 58 biopharma IPOs launched through the third quarter of 2020 was $215.5m and the average return for investors who bought shares in those offerings was 49.4%.

Of those 58 offerings, the average amount raised by the 37 drug developers trading in positive territory through the third quarter was $214.4m – excluding biopharma royalty investor *Royalty Pharma plc*'s $2bn offering – while the average amount raised by the 20

IPO Update: 58 Drug Developers Raised $12.5bn Through Q3

By Mandy Jackson

biopharma firms trading below their IPO values as of early October was $130.6m.

Of course, there always are outliers: *Lantern Pharma, Inc* raised just $26.3m but its stock was up nearly 32% from its IPO price as of 5 October, while *Poseida Therapeutics, Inc.* grossed $224m but had fallen more than 45% from its IPO value.

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The average return for companies that went public in the US through the end of September was 49.4% as of 5 October. The fourth quarter started with three additional initial public offerings on 1 October.

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But looking at the broader performance trend may have convinced IN8bio, Inhibikase and Compass Therapeutics to pursue other financing alternatives, since all three companies planned to raise less than $100m in their first-time offerings. It is also possible that they are waiting for the end of stock market instability related to rising COVID-19 case numbers and the US presidential election.

Cambridge, MA-based Compass Therapeutics – not to be confused with *COMPASS Pathways*, which did go public this year – completed a reverse merger with the special purpose acquisition corporation (SPAC) Olivia Ventures Inc. in June and concurrently raised $60m in a private placement of stock to fund development of its next-generation antibodies for the treatment of cancer. (Also see "*Finance Watch: Up, Up And Away – Biopharma Stocks Keep Rising*" - Scrip, 3 Jul, 2020.)

However, Compass Therapeutics shares are not publicly traded, so before the company withdrew its IPO filing it planned to join the Nasdaq with an offering of 9 million shares at $5 to $6 each, which would have grossed up to $62.1m, including the sale of extra shares to meet overallotments.

IN8bio in New York is developing allogeneic, autologous and genetically modified gamma-delta T cell therapeutics; its lead autologous product candidate known as INB-200 is being tested in a Phase I clinical with top-line results expected in 2021 and its lead allogeneic candidate is in Phase I testing for acute leukemia with top-line data projected for 2022. Before postponing its IPO, IN8bio planned to raise up to $91.6m (including overallotments) through the sale of 4.7 million shares at $15 to $17 each.

Atlanta-based Inhibikase planned a modest IPO of just 1.4 million shares at $10 to $12 each, which would have grossed up to $17.25m, including overallotments, before it postponed the offering. The proceeds would have funded ongoing preclinical and early clinical development of IkT-148009, a c-Abl kinase inhibitor designed to clear alpha-synuclein from the brain and gastrointestinal tract to stop progression and restore function in Parkinson's disease. Its competitors in this early-stage field include South Korea's *1ST Biotherapeutics, Inc.* (Also see

"*1ST Bio Bets On BBB-Penetrating C-ABL Inhibitor As Potential Disease-Modifying Parkinson's Drug*" - Scrip, 31 May, 2018.)

But while Inhibikase, Compass Therapeutics and IN8bio have put their IPO plans on hold, biopharma firms continue to enter the IPO queue in the US and go public in ex-US markets.

The women's cancer drug developer *Olema Pharmaceuticals, Inc.* filed paperwork with the US Securities and Exchange Commission (SEC) on 16 November in support of a future offering to raise up to $170m. Before the weekend, the oncology-focused firms *Kinnate Biopharma Inc.* and *BioAtla, Inc.*, as well as the chronic disease specialist *Sigilon Therapeutics, Inc.*, filed paperwork with the SEC in support of IPOs that could raise up to $100m each.

Olema is not hurting for cash, given that it revealed a $54m series B venture capital round in July and an $85m series C round on 1 October. (Also see "*Finance Watch: Big VC Money Backs Tech-Enabled Drug Discovery*" - Scrip, 2 Oct, 2020.) Similarly, Kinnate closed a $98m series C round in August. (Also see "*Kinnate Raises $98m To Take Kinase Inhibitors Into The Clinic*" - Scrip, 26 Aug, 2020.) Continuing the theme, BioAtla closed a $72.5m series C round in July. (Also see "*Finance Watch: As Exit Values Rise, More Money Flows Into VC Investments*" - Scrip, 15 Jul, 2020.) Also, Sigilon completed an $80.3m series B round in March. (Also see "*Finance Watch: iTeos, Pandion And Aspen Show COVID-19 Hasn't Slowed VC Deals Yet*" - Scrip, 1 Apr, 2020.)

Sixteen companies have gone public in the US so far during the fourth quarter of 2020, bringing the year's total to 74 versus the 2019 total of 50 biopharma IPOs. There have been none so far in November, however; the three most recent drug developer IPOs were launched at the end of October by *Atea Pharmaceuticals, Inc.*, *Galecto Inc.* and *SQZ Biotechnologies Company*. (Also see "*Finance Watch: Joe Jimenez Ventures Into Start-Up World Via Aditum*" - Scrip, 2 Nov, 2020.)

IPOs outside the US also continue to attract investors. Most recently, *JW Therapeutics Co., Ltd* raised $300m in an offering on the Hong Kong Stock Exchange. (Also see "*China Cell Therapy Party On: $500m+ Raised In JW IPO, Other Rounds*" - Scrip, 5 Nov, 2020.)

Biocon, BMS, Epizyme Debt Deals And Other Financial Updates

After prior investments by private equity firms True North and Tata Capital Growth Fund, marquee investor Goldman Sachs is backing *Biocon, Ltd.*'s biosimilars arm Biocon Biologics Ltd.

Goldman Sachs is making a capital injection of INR11.25bn ($151.3m) in Biocon Biologics; in return, the US investment bank will receive optionally convertible debentures at a post-money equity valuation of $3.94bn. Goldman Sachs' endorsement is important as Biocon Biologics, led by ex-*Roche Holding AG* executive Christiane Hamacher as CEO, builds up a high-profile investor base ahead of a potential IPO.

Biocon's chair and managing director Kiran Mazumdar-Shaw said the transaction is a part of the overall strategic plan of value creation for shareholders through Biocon Biologics. Biocon has in the past indicated that an IPO for Biocon Biologics was expected "in the next two to three years;" it previously took its research services arm *Syngene* public.

The capital from Goldman Sachs will be invested in R&D and manufacturing as well as to establish a global commercial footprint, Biocon said on 7 November. True North, which has long been associated with the Biocon group, invested around $75m in Biocon Biologics earlier this year for a 2.44% stake. (Also see "*Biocon Rings In 2020 With Gusto, PE Investment In Biologics Arm*" - Scrip, 7 Jan, 2020.) Tata Capital Growth Fund followed in July with an investment of around $30m in exchange for a 0.85% minority stake, though more pre-IPO placements can't be ruled out. (Also see "*Biocon Biologics Receives Further Investment As Value Hits $3.5bn*" - Generics Bulletin, 31 Jul, 2020.)

Goldman Sachs noted that global growth of biosimilars and collaborative regulatory pathways are taking place at a rapid pace to drive market competition, budget sustainability for health care systems and improved patient access to treatments. The bank noted that Biocon Biologics is well-positioned to continue to grow and be a major global player in this segment.

Biocon recently has underscored that COVID-19 put significant pressure on health care systems across the world and that it believes access to affordable biosimilars will play a bigger role going forward. It expects to work with governments, health care authorities and international organizations to make its products available to patients across the world. (Also see "*Biocon Sees Recovery In Biosimilars, Scope To Address Affordability In US*" - Scrip, 27 Jul, 2020.) Biocon Biologics and partner *Mylan N.V.* have already launched three products in the US: Ogivri (trastuzumab-dkst), Fulphila (pegfilgrastim-jmdb) and Semglee (insulin glargine). (Also see "*Muted Q2 But Biocon Confident Of Insulin Glargine's Onward US March*" - Scrip, 26 Oct, 2020.)

Mylan recently completed its merger with *Pfizer Inc.*'s Upjohn business to become Viatris. (Also see "*Viatris Plots 'Significant' Restructuring As Mylan-Upjohn Merger Completes*" - Generics Bulletin, 16 Nov, 2020.)

In other public company financial and strategic updates:

- *Bristol Myers Squibb Company* priced an offering of $7bn worth of senior unsecured notes on 9 November to help fund its $13.1bn acquisition of *MyoKardia, Inc.*, which closed on 17 November. (Also see "*BMS Buys MyoKardia, Plans To Use Eliquis Experience To Grow Mavacamten*" - Scrip, 5 Oct, 2020.) The offering consisted of 0.537% notes due in 2023 with an aggregate principal amount of $1.5bn, 0.75% notes due in 2025 totaling $1bn, another $1bn worth of notes with a 1.125% interest rate and due in 2027, notes due in 2030 with a 1.45% interest rate totaling $1.25bn, 2.35% notes due in 2040 with an aggregate principal

amount of $750m, and $1.5bn worth of 2.55% notes due in 2050.

- Cambridge, MA-based *Epizyme, Inc.* said on 6 November that it entered into an amended and restated agreement with Pharmakon Advisors LP, an affiliate of Royalty Pharma, to expand its loan facility and draw down $150m in debt; the initial agreement was forged in November 2019. The firms' initial agreement gave Epizyme access to $270m in funding. (Also see "*Finance Watch: As US IPO Market Gets More Challenging, Two Companies Opt Out*" - Scrip, 12 Nov, 2019.) Epizyme accessed $70m initially and $50m in February of this year. (Also see "*Finance Watch: Coronavirus-Related Stock Market Meltdown Didn't Stop Passage Bio IPO*" - Scrip, 3 Mar, 2020.) With the final $150m drawdown, the company says it has enough cash on hand to fund its operations into 2023. The cash will fund commercialization and ongoing development of Tazverik (tazemetostat), a methyltransferase inhibitor that won US Food and Drug Administration approval for two follicular lymphoma indications in June. (Also see "*Keeping Track: Keytruda Claims First TMB-Based Cancer Indication; TG Therapeutics Submits First Umbralisib NDA*" - Pink Sheet, 21 Jun, 2020.)

- *Five Prime Therapeutics, Inc.* in South San Francisco grossed $173.9m from the sale of 8.3 million shares at $21 each in an offering that closed on 17 November. The proceeds will fund ongoing clinical development of bemarituzumab and FPT155, preclinical and clinical development of FPA157, and late-stage research programs, among other expenses. Five Prime launched the offering a few days after it reported positive Phase II results for FGFR2b inhibitor bemarituzumab in the treatment of HER2-negative gastric cancer. FPT155 is a soluble CD80 fusion protein that is being tested in multiple tumor setting in a Phase Ia study. FPA157 is an anti-CCR8 antibody in Phase Ib for the treatment of breast, ovarian and endometrial cancers.

Five Prime Lands Blow On Gastric Cancers With FGFR2b Antibody

By John Davis

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A potential first-in-class FGFR2b-targeted monoclonal antibody, bemarituzumab, has shown top-line benefits in the Phase II FIGHT study in advanced gastric or gastroesophageal junction cancers.

Read the full article here

- Lexington, MA-based *Keros Therapeutics* grossed $149.5m from the sale of 2.99 million shares at $50 each in an offering that closed on 17 November. Keros, which is developing treatment for hematological and musculoskeletal diseases, went public in April at $16 per share. (Also see "*IPO Update: Biopharma Stands Out Among Gloomy US Market*" - Scrip, 15

Apr, 2020.) The company is focused on the TGF-beta family of proteins involved in red blood cell and platelet production as well as growth, repair and maintenance of muscle and bone. Its lead development programs are KER-050 for the treatment of cytopenias, including anemia and thrombocytopenia, in myelodysplastic syndromes (Phase II) and myelofibrosis (Phase I); KER-047 for anemia resulting from iron imbalance and for fibrodysplasia ossificans progressiva (both in Phase I); and the preclinical asset KER-012 for disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for pulmonary arterial hypertension.

- *Aquestive Therapeutics, Inc.* in Warren, NJ said on 3 November that it entered into a royalty monetization agreement with an affiliate of Marathon Asset Management for up to $125m. Marathon's investment entitles the firm to receive all of Aquestive's royalties from *Sunovion Pharmaceuticals Inc.*'s Kynmobi (apomorphine HCI) sublingual film, which was approved in the US in May for acute, intermittent treatment of "off" episodes in Parkinson's disease. (Also see "*Sunovion Plans September Launch For Parkinson's 'Off' Episode Drug Kynmobi*" - Scrip, 24 May, 2020.) Aquestive will receive $40m from Marathon initially and up to $85m based on the achievement of certain milestones. Aquestive will use the funding to pay down debt and fund its drug development programs. The company had a setback in September when the US FDA issued a complete response letter for Libervant (diazepam) buccal film for the management of seizure clusters. (Also see "*Keeping Track: Disappointment For Mesoblast And Aquestive; Opdivo/Yervoy Add Mesothelioma Claim; Pediatric Approvals*" - Pink Sheet, 2 Oct, 2020.)

- *ORIC Pharmaceuticals, Inc.* in South San Francisco and San Diego grossed $133.3m from the sale of 5.8 million shares at $23 each in an offering that closed on 17 November. The company, which is focused on "overcoming resistance in cancer" (ORIC), went public in April at $16 per share. (Also see "*Finance Watch: ORIC Raises $120m In Another Pandemic Era Biopharma IPO*" - Scrip, 24 Apr, 2020.) ORIC's lead product candidate ORIC-101 is a small molecule antagonist of the glucocorticoid receptor that is being tested in two separate Phase Ib trials in combination with Xtandi (enzalutamide) in metastatic prostate cancer and Abraxane (nab-paclitaxel) in advanced or metastatic solid tumors. Additional drugs in development include CD73 inhibitor ORIC-533; ORIC-944, an allosteric inhibitor of polycomb repressive complex 2 (PRC2) via the EED subunit known for prostate cancer; and ORIC-114, an inhibitor of EGFR and HER2 exon 20 insertion mutations for genetically defined cancers.

- *Hutchison China MediTech Limited* (Chi-Med) said on 17 November that the Canada Pension Plan Investment Board paid $30 per American depository share (ADS) to invest $100m in the company. The equity investment will help Chi-Med fund commercialization of surufatinib and savolitinib in China, where the drugs are pending approval, and submission of surufatinib in the US during the next six months. The company – operating in China from

Shanghai and Hong Kong and in the US in Florham Park, NJ – has nine cancer drug candidates in clinical development globally. Surufatinib targets VEGF receptors 1-3, FGFR1 and CSF-1R, while savolitinib is a MET inhibitor. Chi-Med is partnered with *Eli Lilly and Company* on its VEGFR1/2/3 inhibitor Elunate (fruquintinib). (Also see "*Chi-Med Extends Oncology Commercial Reach To Realize China Potential*" - Scrip, 31 Jul, 2020.)

- Bedford, MA-based *Homology Medicines, Inc.* said on 9 November that Pfizer made a $60m equity investment in the company, purchasing 5 million shares at $12 each; the company went public at $16 per share in 2018. (Also see "*IPO Update: Will Declining Returns Slow Fast Pace Of Biopharma Offerings?*" - Scrip, 3 Apr, 2018.) Homology recently announced positive results from the dose-escalation phase of its Phase I/II pheNIX clinical trial of the gene therapy HMI-102 in the treatment of adults with phenylketonuria (PKU). It granted Pfizer a right of first refusal on future transactions involving HMI-102 and the gene-editing therapy HMI-103 for the treatment of children with PKU. Seng Cheng, SVP and chief scientific officer of Pfizer's rare disease research unit, will join Homology's scientific advisory board to participate in matters related to the development of the two PKU programs.

- Boston-based *Stealth BioTherapeutics Inc.* said on 4 November that it received the first $20m in financing under a development funding agreement for up to $35m in funding from Morningside Ventures. Stealth is developing elamipretide for diseases involving mitochondrial dysfunction and will receive the final $15m in funding under the agreement with Morningside based on the achievement of milestones for the company's geographic atrophy and Barth syndrome programs. Additional investors may participate in additional closings for up to $35m in further funding. The proceeds will support an ongoing Phase IIb trial of elamipretide in geographic atrophy, the filing of an NDA in Barth syndrome and expansion into other rare cardiomyopathies and mitochondrial diseases. Stealth partnered with *Alexion Pharmaceuticals Inc.* on elamipretide in October of last year. (Also see "*Deal Watch: GSK Furthers Cancer Gene Therapy Plans Via Lyell Collaboration*" - Scrip, 10 Oct, 2019.)

- *Destiny Pharma plc* of the UK unveiled an £11.5m ($15.1m) fundraising round on 9 November, principally through the issuance of new shares. The cash is being used to acquire the global rights to NTCD-M3, a Phase III-ready candidate for the prevention of *Clostridium difficile* recurrence from NTC, a vehicle for research developed by infectious diseases specialist Dale Gerding. Destiny said that the compound, which has completed a Phase II trial in 173 patients, appears superior to current treatments and drugs in development for *C. difficile* infection recurrence. The financing comes a couple of months after Destiny teamed up with *SporeGen Ltd.* to co-develop its SPOR-COV product, which contains a proprietary formulation of *Bacillus* bacteria that will be administered via nasal spray for potential protection from COVID-19. (Also see "*Destiny And SporeGen Back Nasal Spray Over Vaccine To Tackle COVID-19*" - Scrip, 9 Sep, 2020.)

- The penny stock *Synthetic Biologics, Inc.* revealed on 16 November that it engaged Alliance Global Partners to evaluate the company's strategic alternatives. The Rockville, MD-based company's stock has traded well below $1 per share throughout 2020 and closed at $0.35 on 17 November. It had just $6m in cash on hand at the end of the third quarter, which would last a few more quarters at the current spending rate of $2.1bn, but Synthetic Biologics plans to begin a Phase Ib/IIa clinical trial in the first quarter of 2021 for SYN-004 (ribaxamase). The oral enzyme is designed to prevent dysbiosis of the gut microbiome in order to prevent acute-graft-versus-host disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients. The drug failed in a Phase III *C. difficile* study in 2018. (Also see "*Synthetic Biologics' Ribaxamase Setback Shows Difficulty Of C. Difficile Development*" - Scrip, 23 Apr, 2018.)

- The long-troubled maker of weight loss drug Qsymia (phentermine and topiramate), *Vivus, Inc.*, is progressing through Chapter 11 bankruptcy and will become a wholly owned subsidiary of IEH Biopharma LLC, one of its debt holders. Campbell, CA-based Vivus said on 13 November that it is seeking bankruptcy court approval of its second amended Chapter 11 plan of reorganization. Nasdaq de-listed Vivus's stock in July and its shares began trading on the over-the-counter market at that time. The company previously revealed in June that it was renegotiating its debt with IEH. (Also see "*Finance Watch: Four IPOs In One Week, And Legend Is Year's Largest So Far*" - Scrip, 5 Jun, 2020.)

[Editor's Note: This article was updated on 21 January 2021 to note there were 74 IPOs in the US as of 17 November.]