Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-37500

Chiasma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**76-0722250**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

140 Kendrick Street, Building C East
Needham, Massachusetts 02494
(Address of principal executive office) (Zip Code)

(617) 928-5300
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

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, $0.01 par value	**CHMA**	**NASDAQ Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 5, 2020, there were 57,802,283 shares of the registrant's Common Stock, $0.01 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements include all matters that are not related to present facts or current conditions or that are not historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. The words “anticipate,” “believe,” “could,” “continue,” “should,” “predict,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “will,” “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- our expected commercial launch timing of MYCAPSSA in the United States, if the U.S. Food and Drug Administration, or the FDA, accepts our manufacturing supplement, or CBE-30 supplement, to our approved NDA;
- our expectations regarding the FDA’s review and acceptance of our CBE-30 supplement and the second manufacturing supplement we plan to submit;
- our ability to obtain supply of sufficient amounts of octreotide capsules to support our planned commercial launch in the United States and clinical trials;
- our views as to our readiness for commercial launch of MYCAPSSA in the United States, including our plans with respect our customer-facing team, the nature of our planned commercialization activities and strategy, our pricing of MYCAPSSA, and related assumptions;
- our views as to potential future results of our commercialization efforts in the United States with respect to MYCAPSSA, including our expectations with respect to the scope, level and availability of reimbursement by private and government payors;
- our development of octreotide capsules for the treatment of acromegaly;
- our efforts to potentially obtain regulatory approval of octreotide capsules in the European Union by conducting the MPOWERED Phase 3 clinical trial;
- the timing and receipt and announcement of top-line and other clinical data, including our ability to release top-line data from the MPOWERED trial during the fourth quarter of 2020;
- the therapeutic benefits, effectiveness and safety of octreotide capsules;
- our estimates of the size and characteristics of the markets that may be addressed by octreotide capsules;
- the commercial success and market acceptance of octreotide capsules or any future product candidates that are approved for marketing in the United States or other countries;
- our ability to generate future revenue;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which octreotide capsules have been developed to treat;
- our ability to leverage our Transient Permeability Enhancer, or TPE, platform to develop and commercialize novel oral product candidates incorporating peptides that are currently only available in injectable or other non-absorbable forms;
- the possibility that competing products or technologies may make MYCAPSSA, other product candidates we may develop and commercialize or our TPE technology obsolete;
- our ability to secure collaborators to license, manufacture, market and sell octreotide capsules or any products for which we receive regulatory approval in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our product development and operational plans generally; and
- our estimates and expectations regarding our capital requirements, cash and expense levels and liquidity sources.

These forward-looking statements are not exhaustive. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events

and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and our prior filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “we,” “us”, “our” and “Chiasma” refer to Chiasma, Inc. and our subsidiaries. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including “Chiasma,” “TPE”, “MYCAPSSA” and our corporate logo. Other trademarks or service marks that may appear in this Quarterly Report on Form 10-Q are the property of their respective holders. For convenience, we do not use the ® and ™ symbols in each instance in which one of our trademarks appears throughout this Quarterly Report on Form 10-Q, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto. We do not intend to use or display other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Chiasma, Inc.

INDEX

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Chiasma, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2020	December 31, 2019
	(in thousands except share data)	
Assets		
Current assets		
Cash and cash equivalents	$ 52,194	$ 27,855
Marketable securities	14,893	64,520
Prepaid expenses and other current assets	3,741	3,881
Total current assets	70,828	96,256
Property and equipment, net	617	334
Other assets	2,521	2,236
Restricted cash	20,000	—
Total assets	$ 93,966	$ 98,826
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,079	$ 3,253
Accrued expenses	8,148	7,576
Other current liabilities	716	546
Total current liabilities	15,943	11,375
Deferred royalty obligation	24,601	—
Long-term liabilities	1,444	1,682
Total liabilities	41,988	13,057
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.01 par value; authorized 125,000,000 shares at June 30, 2020 and December 31, 2019; issued and outstanding 42,268,932 shares at June 30, 2020 and 42,078,416 shares at December 31, 2019	423	421
Preferred stock, $0.01 par value; authorized 5,000,000 shares; none outstanding	—	—
Additional paid-in capital	360,977	358,245
Accumulated other comprehensive income	26	37
Accumulated deficit	(309,448)	(272,934)
Total stockholders' equity	51,978	85,769
Total liabilities and stockholders' equity	$ 93,966	$ 98,826

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands except share and per share data)			
Operating expenses:				
General and administrative	$ 10,665	$ 2,644	$ 18,247	$ 5,094
Research and development	9,672	5,522	17,797	11,993
Total operating expenses	20,337	8,166	36,044	17,087
Loss from operations	(20,337)	(8,166)	(36,044)	(17,087)
Interest and other income, net	128	341	526	525
Interest expense	(907)	—	(907)	—
Loss before income taxes	(21,116)	(7,825)	(36,425)	(16,562)
Provision for income taxes	12	15	89	28
Net loss	(21,128)	(7,840)	(36,514)	(16,590)
Earnings per share				
Basic	$ (0.50)	$ (0.25)	$ (0.86)	$ (0.59)
Diluted	$ (0.50)	$ (0.25)	$ (0.86)	$ (0.59)
Weighted-average shares outstanding:				
Basic	42,267,507	31,597,698	42,227,601	28,051,856
Diluted	42,267,507	31,597,698	42,227,601	28,051,856

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Net loss	$ (21,128)	$ (7,840)	$ (36,514)	$ (16,590)
Other comprehensive income (loss):				
Unrealized gain (loss) on available for sale securities, net	23	50	(11)	68
Total other comprehensive income (loss):	23	50	(11)	68
Comprehensive loss	$ (21,105)	$ (7,790)	$ (36,525)	$ (16,522)

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	(in thousands except share data)					
Balance, December 31, 2019	42,078,416	$ 421	$358,245	$ 37	$ (272,934)	$ 85,769
Stock-based compensation	—	—	1,162	—	—	1,162
Exercise of stock options	186,925	2	230	—	—	232
Other comprehensive loss	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	(15,386)	(15,386)
Balance, March 31, 2020	42,265,341	423	359,637	3	(288,320)	71,743
Stock-based compensation	—	—	1,335	—	—	1,335
Exercise of stock options	3,591	—	5	—	—	5
Other comprehensive income	—	—	—	23	—	23
Net loss	—	—	—	—	(21,128)	(21,128)
Balance, June 30, 2020	42,268,932	$ 423	$360,977	$ 26	$ (309,448)	$ 51,978

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	(in thousands except share data)					
Balance, December 31, 2018	24,456,120	$ 245	$270,509	$ (16)	$ (236,614)	$ 34,124
Stock-based compensation	—	—	622	—	—	622
Exercise of stock options	33,839	—	3	—	—	3
Additional paid in capital on account of vested portion of restricted stock	—	—	16	—	—	16
Other comprehensive income	—	—	—	18	—	18
Net loss	—	—	—	—	(8,750)	(8,750)
Balance, March 31, 2019	24,489,959	245	271,150	2	(245,364)	26,033
Stock-based compensation	—	—	627	—	—	627
Exercise of stock options	24,110	—	26	—	—	26
Issuance of common stock in follow-on offering, net	7,263,158	73	32,160	—	—	32,233
Other comprehensive income	—	—	—	50	—	50
Net loss	—	—	—	—	(7,840)	(7,840)
Balance, June 30, 2019	31,777,227	$ 318	$303,963	$ 52	$ (253,204)	$ 51,129

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Operating Activities:		
Net loss	$(36,514)	$(16,590)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	73	29
Stock-based compensation	2,497	1,249
Accretion on marketable securities, net	(94)	(278)
Non-cash lease expense	247	87
Amortization of debt discount and issuance costs	63	—
Benefit for deferred income taxes	(8)	(13)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(127)	1,093
Insurance Recovery (Note 9)	—	18,288
Accounts payable and accrued expenses	5,762	(1,237)
Settlement Liability (Note 9)	—	(18,750)
Other assets	(689)	54
Other current and long-term liabilities	(162)	(40)
Net cash used in operating activities	(28,952)	(16,108)
Investing Activities:		
Purchases of marketable securities	(8,927)	(40,382)
Maturities of marketable securities	58,637	31,750
Purchases of property and equipment	(356)	(14)
Net cash provided by (used in) investing activities	49,354	(8,646)
Financing Activities:		
Proceeds from the issuance of common stock, net	—	32,233
Exercise of stock options	237	29
Payments of short-term borrowing	(838)	—
Proceeds from deferred royalty obligation, net	24,538	—
Net cash provided by financing activities	23,937	32,262
Net increase in cash, cash equivalents and restricted cash	44,339	7,508
Cash, cash equivalents and restricted cash, beginning of period	27,855	13,060
Cash, cash equivalents and restricted cash, end of period	$ 72,194	$ 20,568
Reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets		
Cash and cash equivalents	$ 52,194	$ 20,568
Restricted cash	20,000	—
Total cash, cash equivalents and restricted cash	$ 72,194	$ 20,568

See accompanying notes to these unaudited condensed consolidated financial statements.

CHIASMA, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
June 30, 2020

1. Description of Business and Summary of Significant Accounting Policies

Chiasma, Inc. is a commercial stage biopharmaceutical company incorporated in 2001 under the laws of the State of Delaware. Chiasma, Inc. is headquartered in Massachusetts and has two wholly owned subsidiaries; Chiasma (Israel) Ltd., and Chiasma Securities Corp, collectively referred to as "the Company," "we," "us," "our" or "Chiasma". We are focused on developing and commercializing oral therapies to improve the lives of patients who face challenges associated with their existing treatments for rare and serious chronic disease. Employing our Transient Permeability Enhancer ("TPE") technology platform, we seek to develop oral medications that are currently available only as injections. On June 26, 2020, we received approval from the U.S. Food and Drug Administration ("FDA") of our oral octreotide capsules product candidate, MYCAPSSA for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. Our planned U.S. commercial launch of MYCAPSSA is expected to commence in the fourth quarter of 2020.

Acromegaly is a rare and debilitating condition that is caused by the body's production of excess growth hormone. Octreotide is an analog of somatostatin, a natural inhibitor of growth hormone secretion. Octreotide capsules have been granted orphan designation in the United States and the European Union for the treatment of acromegaly. We retain worldwide rights to develop and commercialize octreotide capsules.

We are currently conducting an international Phase 3 clinical trial, referred to as MPOWERED, of oral octreotide capsules for the maintenance treatment of adult patients with acromegaly to support regulatory approval in the European Union by the European Medicines Agency ("EMA"). The MPOWERED trial is a global, randomized, open-label and active-controlled 15-month trial initially designed to enroll up to 150 patients. The EMA requested that a minimum of 80 patients who are responders to octreotide capsules per the protocol following the six-month run-in phase be randomized to either remain on octreotide capsules or return to injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months. In June 2019, we completed the enrollment of 146 total patients in MPOWERED and in January 2020 completed the randomization in that trial.

In April 2019, we completed an underwritten public offering of 7,263,158 shares of common stock at $4.75 per share for aggregate net proceeds of approximately $32.2 million after underwriting fees and offering expenses. In August 2019, we completed a follow-on public offering of common stock in which we sold 10,166,427 shares of common stock at $5.50 per share for aggregate net proceeds of approximately $52.3 million after underwriting fees and offering expenses.

In April 2020, we entered into an Open Market Sales Agreement ("ATM Agreement") for "at the market offerings" with Jefferies LLC ("Jefferies"), under which we may offer and sell from time to time shares of our common stock having an aggregate offering price of up to $60.0 million through Jefferies, acting as our sales agent or principal. To date, we have not sold any common stock under the ATM Agreement.

In April 2020, we entered into a Revenue Interest Financing Agreement (the "Revenue Interest Financing Agreement") with Healthcare Royalty Partners IV, L.P. ("HCR") for up to $75.0 million. The initial funding of $25.0 million, less certain transaction expenses, was completed in April 2020 and the second funding of $25.0 million, less certain transaction expenses, was completed in July 2020 (see Note 6).

In July 2020, we completed an underwritten public offering of 15,125,000 shares of common stock and pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 5,000,000 shares of common stock for aggregate net proceeds of approximately $75.5 million less underwriting fees and offering expenses. The Pre-Funded Warrants are immediately exercisable at an exercise price per share of $0.0001.

We have incurred substantial operating losses since inception, and we expect our operating losses and negative operating cash flows to continue for the foreseeable future. We are heavily dependent on the commercial success of MYCAPSSA in the United States and the regulatory approval and subsequent commercial success of MYCAPSSA in the European Union, both of which may never occur. We plan to continue to invest in our commercial launch, the manufacturing of octreotide capsules for market consumption, as well as invest in manufacturing scale-up activities, and continuing the open label extension portion of our international Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly and to continue to conduct our international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly and, if the MPOWERED trial results are positive, prepare and submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking potential regulatory approval of octreotide capsules as a treatment for acromegaly in the European Union. The FDA approved MYCAPSSA on June 26, 2020 and,

in July 2020, we completed an underwritten public offering of our common stock and Pre-Funded Warrants for aggregate net proceeds of approximately $75.5 million and received the Revenue Interest Financing Agreement's second tranche funding of $25.0 million, less certain transaction expenses. We currently expect our existing cash, cash equivalents and marketable securities to fund our operations for at least one year after the date these condensed consolidated financial statements are issued.

Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. We plan to continue to fund our losses from operations and capital funding needs from existing balances of cash, cash equivalents and marketable securities, the anticipated $15.0 million of additional funding from HCR following the first commercial sale of MYCAPSSA and potentially through equity financings. We may also opportunistically consider license and collaboration agreements with potential partners or convertible debt financing to the extent such sources are identified and available. If our anticipated U.S. revenues are insufficient to fund our operations to attaining and sustaining profitability, additional financing may be required. Such financing, if required, may not be available on a timely basis on terms acceptable to us, or at all. If we are not able to secure adequate additional funding when required, we may be forced to make reductions in spending, extend payment terms with suppliers, suspend or curtail our development opportunities, or it may negatively impact our ability to adequately fund or delay our potential commercial preparations or launch readiness outside the United States if the MPOWERED trial results are positive and MYCAPSSA is approved by the EMA. Any of these actions could materially harm our business, results of operations and future prospects. Failure to successfully commercialize octreotide capsules in acromegaly will prevent us from achieving profitability and positive cash flows, which could raise significant concerns about our continued viability as a business.

Basis of Presentation

We have prepared the accompanying unaudited condensed consolidated financial statements pursuant to the rules and regulations of the SEC regarding interim financial reporting. Accordingly, certain information and footnote disclosures required by accounting principles generally accepted in the United States ("U.S. GAAP") for annual financial statements have been condensed or omitted. The information included in this quarterly report on Form 10-Q should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2019. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements but does not include all disclosures required by U.S. GAAP. In the opinion of management, we have prepared the accompanying unaudited condensed consolidated financial statements on the same basis as our audited financial statements, and these financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results of the interim periods presented. Interim results are not necessarily indicative of results for a full year or for any other subsequent interim period.

Cash Equivalents

Cash equivalents consist of highly liquid instruments that mature within three months or less from the date of purchase.

Marketable Securities

Our investments primarily consist of commercial paper and corporate and government debt securities. These marketable securities are classified as available-for-sale, and as such, are reported at fair value on our condensed consolidated balance sheets. Unrealized holding gains and losses are reported within accumulated other comprehensive income (loss) as a separate component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization, together with interest on securities, are included in interest and other income, net, on our condensed consolidated statements of operations.

If a decline in the fair value of a marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. The cost of securities sold is based on the specific identification method.

Concentrations of credit risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. We routinely maintain deposits in financial institutions in excess of government insured limits. Management believes that we are not exposed to significant credit risk as our deposits are held at financial institutions that management believes to be of high credit quality and we have not experienced any

significant losses in these deposits. We regularly invest excess operating cash in deposits with major financial institutions and money market funds and in notes issued by the U.S. government, as well as in fixed income investments and U.S. bond funds, both of which can be readily purchased and sold using established markets. We believe that the market risk arising from our holdings of these financial instruments is mitigated based on the fact that many of these securities are either government backed or of high credit rating.

Inventory

Prior to FDA approval of MYCAPSSA, all costs related to the manufacturing of MYCAPSSA that could potentially be available to support the planned U.S. commercial launch were charged to research and development expense in the period incurred. Generally, inventory may be capitalized if it is probable that future revenues will be generated from the sale of the inventory and that these revenues will exceed the cost of the inventory. Through the FDA approval date of MYCAPSSA, we expensed all of our manufacturing costs due to the high risk inherent in drug development and uncertainty as to whether MYCAPSSA would be approved. The manufacturing-related costs incurred following our June 26, 2020 FDA approval of MYCAPSSA were immaterial to our condensed consolidated financial statements. We will begin to capitalize our manufacturing-related costs to inventory starting July 1, 2020.

We capitalize the costs to manufacture our products incurred after regulatory approval when, based on our judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. In connection therewith, we value our inventories at the lower of cost or estimated net realizable value. We determine the cost of our inventories, which includes amounts related to active pharmaceutical ingredient and other raw materials, third party manufacturing costs and other overhead costs, on a first-in, first-out basis. Inventories that may be used for either research and development or commercial sale are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is intended to be used for research and development, it is expensed as research and development once that determination is made.

Prospectively, on a quarterly basis, we will review inventory quantities on hand and analyze the provision for excess and obsolete inventory based primarily on remaining product shelf life and our estimated sales forecast which is based on anticipated future demand. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, and patient usage. Our estimates of future product demand may prove to be imprecise and changes in estimates will result in a change to the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

Deferred Royalty Obligation

We treat the deferred royalty obligation, as discussed further in Note 6, as a debt obligation, amortized under the effective interest rate method over the estimated life of the agreement. We recognize interest expense thereon using the effective rate, which is based on our current estimates of future revenues over the life of the arrangement. In connection therewith, we periodically assess our expected revenues using internal projections, impute interest on the carrying value of the deferred royalty obligation, and record interest expense using the effective interest rate. To the extent our estimates of future revenues are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will account for any such changes by adjusting the effective interest rate on a prospective basis, with a corresponding impact to the reclassification of our deferred royalty obligation between short- and long-term. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the issuance costs requires that we make estimates that could impact the short-term and long-term classification of such costs, as well as the period over which such costs will be amortized.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes during the reporting period. We base these estimates and assumptions on historical experience when available, and on various factors that we believe to be reasonable under the specific circumstances. Significant estimates relied upon in preparing the accompanying condensed consolidated financial statements include, but are not limited to, accounting for stock-based compensation, income taxes, the fair value of embedded derivatives and our deferred royalty obligation and accounting for certain accruals. We assess the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued new guidance which will require more timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. The new guidance requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The new guidance also requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. On January 1, 2020, we adopted this standard. The adoption of this standard did not have a material impact on our condensed consolidated financial statements.

2. Investments

Our investments consisted of the following as of June 30, 2020 and December 31, 2019:

	As of June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	($ in thousands)			
Money market funds	$ 61,918	$ —	$ —	$ 61,918
Corporate notes	10,095	7	—	10,102
Commercial paper	10,228	19	—	10,247
U.S. treasury shares	2,999	—	—	2,999
Total	$ 85,240	$ 26	$ —	$ 85,266

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	($ in thousands)			
Money market funds	$ 23,012	$ —	$ —	$ 23,012
Corporate notes	45,584	20	—	45,604
Commercial paper	20,899	17	—	20,916
Total	$ 89,495	$ 37	$ —	$ 89,532

As of June 30, 2020, we consider those securities that are in an unrealized loss position as temporary and not due to credit losses. We have the ability to hold such investments until recovery of the fair value. We utilize the specific identification method in computing realized gains and losses. We had no realized gains and losses on our available-for-sale securities for the three and six months ended June 30, 2020 or 2019.

The fair values of our investments by classification in our condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019 were as follows:

	June 30, 2020	December 31, 2019
	($ in thousands)	
Cash and cash equivalents	$ 50,373	$ 25,012
Marketable securities	14,893	64,520
Restricted cash	20,000	—
Total	$ 85,266	$ 89,532

Cash and cash equivalents in the table above exclude cash of $1.8 million and $2.8 million as of June 30, 2020 and December 31, 2019, respectively. The contractual maturity dates of all of our investments are less than one year.

3. Fair Value Measurements of Financial Instruments

Certain assets and liabilities are reported at fair value on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. The fair value accounting guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

- *Level 1* — Quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.
- *Level 2* — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.
- *Level 3* — Inputs that are unobservable for the asset or liability.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The fair value measurements of our financial instruments are summarized in the table below:

	Fair Value Measurements at June 30, 2020			
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($ in thousands)		
Financial assets				
Cash equivalents:				
Money market funds	$ 61,918	$ —	$ —	$61,918
U.S. treasury shares	2,999	—	—	2,999
Corporate notes	—	2,457	—	2,457
Commercial paper	—	2,999	—	2,999
Total cash equivalents	$ 64,917	$ 5,456	$ —	$70,373
Marketable securities:				
Corporate notes	$ —	$ 7,645	$ —	$ 7,645
Commercial paper	—	7,248	—	7,248
Total marketable securities	—	14,893	—	14,893
Total	$ 64,917	$ 20,349	$ —	$85,266
Financial liabilities				
Derivative liabilities	$ —	$ —	$ 1,308	$ 1,308

Description	Fair Value Measurements at December 31, 2019 Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($ in thousands)		
Financial assets				
Cash equivalents:				
Money market funds	$ 23,012	$ —	$ —	$23,012
Corporate notes	—	2,000	—	2,000
Total cash equivalents	$ 23,012	$ 2,000	$ —	$25,012
Marketable securities:				
Corporate notes	$ —	$ 43,604	$ —	$43,604
Commercial paper	—	20,916	—	20,916
Total marketable securities	—	64,520	—	64,520
Total	$ 23,012	$ 66,520	$ —	$89,532

Our cash equivalents are composed of money market funds and U.S. treasury shares and are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our marketable securities consist of corporate notes and commercial paper and are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of June 30, 2020 or December 31, 2019.

In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. We recorded derivative liabilities associated with our deferred royalty obligation, as discussed further in Note 6, of $1.3 million during the three months ended June 30, 2020. There was no change in the fair value of the derivative liabilities during the three months ended June 30, 2020. These derivative liabilities are measured at fair value using an option pricing Monte Carlo simulation model and is included as a component of the deferred royalty obligation. The embedded derivative liabilities are subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of interest and other income, net. The assumptions used in the option pricing Monte Carlo simulation model include: (1) the expected net sales of MYCAPSSA and any of our other future products; (2) our risk-adjusted discount rate that includes a company specific risk premium; (3) our cost of debt; (4) volatility; (5) the probability and timing of a change in control occurring during the term of the instrument; and (6) the probability and timing of an event of default during the term of the instrument. We did not have any Level 3 assets or liabilities being measured at fair value on a recurring basis as of December 31, 2019.

4. Earnings per Share of Common Stock

All common stock warrants and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an anti-dilutive impact due to net losses reported during the three and six months ended June 30, 2020 and 2019.

5. Accrued Expenses

As of June 30, 2020 and December 31, 2019, accrued expenses consisted of the following:

	June 30, 2020	December 31, 2019
	($ in thousands)	
Accrued research and development expenses	$ 3,498	$ 4,219
Accrued general, administrative and other expenses	2,413	1,485
Accrued payroll and employee benefits	2,237	1,872
Total accrued expenses	$ 8,148	$ 7,576

6. Deferred Royalty Obligation

In April 2020, we entered into the Revenue Interest Financing Agreement with HCR whereby HCR will receive payments from us at a tiered percentage (the "Applicable Tiered Percentage") of future net revenues of MYCAPSSA and any of our other future products, including worldwide net product sales and upfront payments and milestones received from third parties under license agreements (the "Revenue Interests"). Under the terms of the agreement, we received $25.0 million, less certain transaction expenses, from HCR in April 2020 and an additional $25.0 million in July 2020 following the FDA approval of MYCAPSSA. We are entitled to receive an additional $15.0 million upon conditions related to commercial drug supply availability and first commercial sale of MYCAPSSA, subject to customary closing conditions. We are also entitled to receive an additional $10.0 million in early 2022 subject to the achievement of a revenue milestone and customary closing conditions. In exchange for the total investment amount ("Investment Amount") received, HCR will receive a tiered royalty starting in the low double digits on worldwide annual net revenues of MYCAPSSA and any other future products, subject to step-downs upon the achievement of certain annual revenues.

HCR's rights to receive the Revenue Interests shall terminate on the date on which HCR has received payments equal to 195% of the funded portion of the Investment Amount including the aggregate of all payments made to HCR as of such date, unless the Revenue Interest Financing Agreement is terminated earlier. If HCR has not received payments equal to the 195% of the funded portion of the Investment Amount by the ten-year anniversary of the initial closing date and no event of default has occurred or is ongoing, among other things, we shall pay HCR an amount equal to the funded portion of the Investment Amount plus a specific annual rate of return in the low to mid-teens less payments previously received. If a change of control of the Company occurs, we must immediately repay HCR the total amount actually funded (including unfunded amounts conditionally eligible to be funded) plus a change of control premium, the amount of which is variable up to 95% based on timing and circumstances of such change of control. Upon the occurrence of an event of default, including the withdrawal, suspension or other termination of the FDA approval of MYCAPSSA as a treatment for acromegaly that continues for sixty days that prevents us from marketing MYCAPSSA, HCR may accelerate payments due under the agreement to the 195% of the funded portion of the Investment Amount.

If HCR has not received 60% of the funded portion of the Investment Amount by September 30, 2023 or 100% of the funded portion of the Investment Amount by September 30, 2024, we must make cash payments sufficient to gross HCR up to such minimum amounts. Further, the Revenue Interest Financing Agreement requires us to maintain a minimum of $20.0 million in securitized cash and investment accounts, which we recorded as restricted cash in the condensed consolidated balance sheet, during any quarter that the trailing four quarters of net revenue of MYCAPSSA is below a certain threshold. Our obligations under the Revenue Interest Financing Agreement are secured by a first priority perfected security interest in all of our Chiasma, Inc. cash and cash equivalents (as defined in the Revenue Interest Financing Agreement), all present and future net revenues of MYCAPSSA and all MYCAPSSA-related assets.

We have evaluated the terms of the deferred royalty obligation and concluded that the features of the Investment Amount are similar to those of a debt instrument. Accordingly, we have accounted for the transaction as long-term debt. We have evaluated the terms of the debt and determined that the repayment of up to 195% of the Investment Amount, less any payments made to date, upon a change of control is an embedded derivative that requires bifurcation from the debt instrument and fair value recognition. In addition, we have determined that the repayment of 195% of the funded portion of the Investment Amount, less any payments made to date, upon an event of default is an embedded derivative that requires bifurcation from the debt instrument and fair value recognition. We determine the fair value of the derivatives using an option pricing Monte Carlo simulation model taking into account the probability and timing of a change of control and an event of default occurring and potential repayment amounts and timing of such payments that would result under various scenarios, as further described in Note 3. The aggregate fair value of the embedded derivative is $1.3 million and is presented in deferred royalty obligation in the condensed consolidated balance sheet. We remeasure the embedded derivative to fair value each reporting period until the time the termination of the Revenue Interest Financing Agreement.

The effective interest rate as of June 30, 2020 was approximately 18%. In connection with the deferred royalty obligation, we incurred debt issuance costs totaling $0.6 million in the six months ended June 30, 2020. Debt issuance costs have been netted against the deferred royalty obligation and are being amortized over the estimated term of the obligation using the effective interest method, adjusted on a prospective basis for changes in the underlying assumptions and inputs. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the issuance costs requires that we make estimates that could impact the short- and long-term classification of these costs, as well as the period over which these costs will be amortized.

The carrying value of the deferred royalty obligation, as presented on the condensed consolidated balance sheet, approximates fair value as of June 30, 2020 and was measured using Level 3 inputs. The estimated fair value was calculated using an option pricing Monte Carlo simulation model with inputs consistent with those used in determining the embedded derivative values as described in Note 3.

7. Warrants

As of December 31, 2019, there were 3,567,015 common stock warrants outstanding with exercise prices ranging from $0.09 per share to $9.13 per share. Such warrants were issued between October 2012 and February 2015 with expiration dates ranging from March 2022 through December 2024. There were no warrants issued or exercised during the six months ended June 30, 2020. There were 3,567,015 outstanding warrants as of June 30, 2020. As described in Note 1, in July 2020, we issued Pre-Funded Warrants in connection with an underwritten public offering to purchase an aggregate of 5,000,000 shares of common stock which are immediately exercisable at an exercise price per share of $0.0001.

8. Stock-based Compensation

In 2008, our board of directors adopted the 2008 Stock Incentive Plan (the "2008 Plan"), which provided for the grant of incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company up to 3,547,741 shares of common stock. Option awards expire 10 years from the grant date and generally vest over four years but vesting conditions can vary at the discretion of our board of directors.

In July 2015, the Company approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which became effective upon our initial public offering. The 2015 Plan allows the grant of incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company initially up to 3,566,296 shares of common stock. In connection with the adoption of the 2015 Plan, no further option grants were permitted under the 2008 Plan and any expirations, cancellations, or terminations under the 2008 Plan are available for issuance under the 2015 Plan. On January 1, 2020, the number of shares reserved and available for issuance under the 2015 Plan increased by 1,683,136 shares of common stock pursuant to a provision in the 2015 Plan that provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2016, by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the board of directors. As of June 30, 2020, the total number of shares authorized for stock award plans is 9,775,418 of which 1,511,498 remain available for grant. There are 7,916,922 stock options outstanding as of June 30, 2020.

Stock-based compensation for the three and six months ended June 30, 2020 and 2019 consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	($ in thousands)			
General and administrative	$ 1,060	$ 360	$ 2,013	$ 671
Research and development	275	267	484	578
Total	$ 1,335	$ 627	$ 2,497	$ 1,249

The fair value of each stock option issued was estimated at the date of grant using the Black-Scholes option model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2020	2019
Expected volatility	85%	98%
Expected term (years)	6.2	6.0
Risk-free interest rate	1.11%	2.09%
Expected dividend yield	0%	0%

We granted approximately 1,736,900 stock options in the six months ended June 30, 2020. The weighted-average grant date fair value per share of stock options granted during the six months ended June 30, 2020 was $3.32. We granted approximately 1,533,000 stock options in the six months ended June 30, 2019. The weighted-average grant date fair value per share of options granted during the six months ended June 30, 2019 was $5.19.

9. Commitments and Contingencies

Manufacturing Commitments

As of June 30, 2020, we had outstanding manufacturing commitments, including the acquisition of API, in the aggregate amount of $25.2 million of which $9.2 million is expected to be incurred in 2020 with the remainder to be incurred throughout 2021. The payments on these commitments will occur following the deliveries of the API or completion of the manufacturing services.

2019 Litigation Settlement

On June 9, 2016, Chiasma, Inc. and certain of our current and former officers were named as defendants in a purported federal securities class action lawsuit filed in the United States District Court for the District of Massachusetts, styled *Gerneth v. Chiasma, Inc., et al*. An amended complaint was filed by the lead plaintiff on February 10, 2017 challenging our statements regarding our first Phase 3 clinical trial methodology and results, and our ability to obtain FDA approval for octreotide capsules, in violation of Sections 11 and 15 of the Securities Act of 1933. The amended complaint added as defendants current and former members of our board of directors, as well as the investment banks that underwrote our initial public offering on July 15, 2015. The plaintiff sought an unspecified amount of compensatory damages on behalf of himself and members of a putative shareholder class, including interest and reasonable costs and expenses incurred in litigating the action, and any other relief the court determines is appropriate. The defendants filed a motion to dismiss the amended complaint on March 27, 2017 and on February 15, 2018, the court denied defendants' motion to dismiss. The defendants filed an answer to the amended complaint on March 30, 2018. On February 27, 2019, the parties agreed to a settlement of all legal claims in which defendants expressly denied that they have committed any act or omission giving rise to any liability under Sections 11 or 15 of the Securities Act of 1933. On March 14, 2019, the court issued an order of preliminary approval of the settlement. As a result of this settlement agreement, we have recorded a litigation settlement liability of $18.8 million as of December 31, 2018. Additionally, we have recorded a litigation insurance settlement recovery receivable of $18.3 million as of December 31, 2018 which represents the estimated insurance claim proceeds from our insurance carriers. On June 27, 2019, the court issued an order of final approval of the settlement. The litigation insurance settlement recovery and litigation settlement liability were settled during the three months ended June 30, 2019.

10. Leases

We determine if an arrangement is a lease at inception. We have operating leases for our office spaces and certain automobiles. Right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The right-of-use asset also includes direct costs incurred and is reduced by lease incentives. Lease agreements with lease and non-lease components are accounted for separately. As our leases do not provide an implicit rate, we use an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. We recognize operating lease expense on a straight-line basis over the lease term.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	($ in thousands)			
The components of lease expense were as follows:				
Operating lease expense	$ 171	$ 57	$ 335	$ 104
Supplemental cash flow information related to leases was as follows:				
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 199	$ 55	$ 271	$ 100
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	$ —	$ 86	$ 94	$ 113

	June 30, 2020 ($ in thousands)
Supplemental balance sheet information related to leases was as follows:	
Right-of-use assets	$ 1,220
Other current liabilities	$ 623
Long-term liabilities	785
Total lease liabilities	$ 1,408
Weighted average remaining lease term—operating leases	26 Months
Weighted average discount rate—operating leases	10.8%

Our lease right-of-use assets are recorded within other assets on our condensed consolidated balance sheets.

Future lease payments under noncancelable leases as of June 30, 2020 are as follows:

	($ in thousands)
Remainder of 2020	$ 388
2021	715
2022	487
Total future minimum lease payments	1,590
Less: imputed interest	(182)
Total	$ 1,408

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the accompanying notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q and our prior filings with the SEC, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial stage biopharmaceutical company focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic disease. Employing our proprietary Transient Permeability Enhancer, or TPE®, technology platform, we seek to develop oral medications that are currently available only as injections. On June 26, 2020, the U.S. Food and Drug Administration, or the FDA, approved MYCAPSSA® (octreotide) capsules for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. MYCAPSSA is the first and only oral somatostatin analog, or SSA, approved by the FDA and the first product approved by the FDA utilizing our TPE technology. The FDA approval of MYCAPSSA was based on the positive results of the randomized, double-blind, placebo-controlled, nine-month Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules, which met the primary endpoint and all four secondary endpoints, as well as safety data from all of Chiasma's Phase 3 clinical trials of MYCAPSSA. We are focused on the commercialization of MYCAPSSA for the treatment of patients with acromegaly in the United States and developing and seeking regulatory approval of MYCAPSSA in the European Union.

Acromegaly is a rare and debilitating condition that results from the body's production of excess growth hormone, which in turn elevates insulin-like growth factor 1, or IGF-1. These elevated hormone levels result in a number of painful and disfiguring symptoms, including some acute, such as headaches, joint pain and fatigue, and some long-term, such as enlarged hands, feet and internal organs, as well as altered facial features. If not treated promptly, acromegaly can lead to serious illness and is associated with premature death, primarily due to cardiovascular disease. Octreotide is an analog of somatostatin, a natural inhibitor of growth hormone secretion. The current standard of care for patients diagnosed with acromegaly and not otherwise cured by surgical removal of the pituitary tumor consists of lifelong, once-monthly injections of an extended release somatostatin analog. Octreotide capsules have been granted orphan designation in the United States and the European Union for the treatment of acromegaly. The worldwide market for injectable somatostatin analogs is approximately $2.8 billion annually. We estimate the global market for SSAs in the treatment of acromegaly at approximately $800 million of which we estimate the U.S. market at approximately $400 million. We retain worldwide rights to develop and commercialize octreotide capsules.

We are also conducting an international Phase 3 clinical trial, or MPOWERED, of oral octreotide capsules for the maintenance treatment of adult patients with acromegaly to support regulatory approval in the European Union. The MPOWERED trial is a randomized, open-label and active-controlled 15-month trial initially designed to enroll up to 150 patients. The European Medicines Agency, or EMA, requested that a minimum of at least 80 patients who are responders to octreotide capsules following the six-month run-in phase be randomized to either remain on octreotide capsules or return to injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months. In June 2019, we completed the enrollment of 146 total patients in MPOWERED. In January 2020, the randomization of patients was completed. Of the 146 patients that entered the six-month run-in phase of the trial, 92 of these patients (or 63%) completed the run-in phase and were deemed to be responders to octreotide capsules per protocol (IGF-1 <1.3 x ULN and GH<2.5 ng/mL). Of the 92 patients who completed the run-in phase, 85 patients have completed the trial and four remain in the nine-month, randomized, controlled phase of the trial. MPOWERED has met the EMA requirement of a minimum of 80 patients randomized into the controlled phase of the trial. The primary endpoint will be calculated with time weighted average analysis, therefore missing monthly IGF-1 values are not anticipated to affect the completion of the primary endpoint analysis. We expect to release top-line data from the MPOWERED trial in the fourth quarter of 2020. If the MPOWERED trial results are positive, we plan to prepare and submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking potential regulatory approval of oral octreotide as a treatment for acromegaly in the European Union.

In March 2020, we commenced enrolling patients in the first industry-sponsored disease state registry for acromegaly in the United States known as the Management of Acromegaly Registry, or MACRO Registry. The MACRO Registry is designed to enroll patients from over 40 planned clinical sites in the United States and collect real-world data on treatment burden and effectiveness of various acromegaly treatments.

We were incorporated in 2001 and commenced active operations in the same year. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our TPE technology, identifying potential drug candidates, undertaking nonclinical studies and, beginning in 2010, conducting clinical trials and preparing for regulatory submissions. In addition, we initiated pre-commercial activities in anticipation of FDA marketing approval of octreotide capsules in June 2020. In July 2015, we completed our initial public offering, or IPO, in which we raised $106.5 million. In April 2019, we completed a follow-on public offering of common stock in which we raised an additional $32.2 million. In August 2019, we completed a follow-on public offering of common stock in which we raised an additional $52.3 million. In April 2020, we entered into a Revenue Interest Financing Agreement, or the Revenue Interest Financing Agreement, with Healthcare Royalty Partners IV, L.P., or HCR for up to $75.0 million. In July 2020, we completed a follow-on public offering which consisted of common stock and pre-funded warrants in which we raised an additional $75.5 million. As of June 30, 2020, our consolidated cash, cash equivalents, marketable securities and restricted cash were $87.1 million, of which $0.4 million was held by Chiasma (Israel) Ltd., our wholly owned Israeli subsidiary. In April 2020, we entered into an Open Market Sales Agreement, or ATM Agreement, for “at the market offerings” under which we may offer and sell from time to time shares of our common stock having an aggregate offering price of up to $60.0 million through Jefferies, acting as our sales agent or principal. To date, we have not sold any common stock under the ATM Agreement.

We have incurred significant operating losses since our inception. Our net loss was $36.5 million for the six months ended June 30, 2020 and $36.3 million for the year ended December 31, 2019. As of June 30, 2020, we had an accumulated deficit of $309.4 million. We expect to incur significant operating losses over the next several years. These losses, combined with prior losses will continue to have an adverse effect on our cash resources, stockholders’ equity and working capital. We plan to invest in our commercial launch, manufacture octreotide capsules for market consumption, as well as invest in manufacturing scale-up activities, and continue the open label extension portion of our international Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly and to continue to conduct our international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly and, if the MPOWERED trial results are positive, prepare and submit an MAA to the EMA, seeking potential regulatory approval of oral octreotide as a treatment for acromegaly in the European Union. Because of the numerous risks and uncertainties facing our company and associated with developing and commercializing pharmaceutical products generally, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. We plan to continue to fund our losses from operations and capital funding needs from existing balances of cash, cash equivalents and marketable securities, the anticipated $15.0 million of additional funding from HCR following the first commercial sale of MYCAPSSA and potentially through equity financings. We may also opportunistically consider license and collaboration agreements with potential partners or convertible debt financing to the extent such sources are identified and available. If our anticipated U.S. revenues are insufficient to fund our operations to attaining and sustaining profitability, additional financing may be required. Such financing, if required, may not be available on a timely basis on terms acceptable to us, or at all. If we are not able to secure adequate additional funding when required, we may be forced to make reductions in spending, extend payment terms with suppliers, suspend or curtail our development opportunities, or it may negatively impact our ability to adequately fund or delay our potential commercial preparations or launch readiness outside the United States if the MPOWERED trial results are positive and MYCAPSSA is approved by the EMA. Any of these actions could materially harm our business, results of operations and future prospects. Failure to successfully commercialize octreotide capsules in acromegaly will prevent us from achieving profitability and positive cash flows, which could raise significant concerns about our continued viability as a business.

COVID-19 Update

In March 2020, the World Health Organization declared the novel strain of coronavirus, or COVID-19, a global pandemic and recommended containment and mitigation measures worldwide. We continue to closely monitor the impact of COVID-19 on our business and have implemented steps to ensure the well-being of our employees as well as the patients and health care professionals involved in the MPOWERED study and the MACRO Registry. At this time, we continue to plan for the approval of the “changes being effected in 30 days” supplement, CBE-30 supplement, which we submitted to the FDA on June 29, 2020 seeking a post-approval change to our FDA-approved new drug application, or NDA, for MYCAPSSA to provide for the approval of our primary commercial API manufacturer and one of its large-scale manufacturing sites. In addition, we have not observed any significant disruptions to our manufacturing supply chain to date. Our MPOWERED trial is progressing as planned and we continue to expect to release top-line data in the fourth quarter of 2020. The COVID-19 pandemic has caused us to modify our business practices, including taking steps to protect our employees and the broader community, such as curtailing or modifying employee travel, reducing access to our offices, moving employees to remote work where appropriate, and cancelling in-person participation in meetings,

events and conferences, while seeking to ensure our ability to execute our planned commercial launch by utilizing digital engagement and remote interaction with potential customers. However, restrictions on and discouragement of travel, access to hospitals and physicians' office, and face-to-face meetings may make it difficult to drive the awareness and adoption of MYCAPSSA. We are unable to predict the impact that COVID-19 will have on our future plans, including timing of FDA approval of our CBE-30 supplement, if any, for commercialization, and our future financial position and operating results due to numerous uncertainties. The duration and severity of the outbreak and its long-term impact on our business cannot be ascertained at this time.

Commercial Manufacturing Supply

We began implementing launch readiness plans in 2019 in preparation for a commercial launch of MYCAPSSA capsules in the United States in the fourth quarter of 2020, pending the FDA's approval of our NDA. Following FDA approval of our NDA and to secure commercial supply of our planned launch, we submitted our CBE-30 supplement on June 29, 2020 to provide for the approval of our primary commercial API manufacturer and one of its large-scale manufacturing sites. At this time, we expect to have sufficient commercial supply of MYCAPSSA to support our planned commercial launch in the fourth quarter of 2020, pending the FDA's timely acceptance of our CBE-30 supplement. Unless the FDA determines that this CBE-30 supplement is not sufficiently complete to permit a substantive review, we expect the FDA will accept the CBE-30 supplement and set a PDUFA target date in the fourth quarter of 2020 for the completion of its review. If the FDA accepts the CBE-30 supplement without delay or exception, we currently expect to begin distributing commercial product as part of our U.S. commercial launch as soon as we have commercial supplies of MYCAPSSA available at our third-party logistics provider. In addition, we also plan to file a second manufacturing supplement to the NDA, which we expect will be a prior approval manufacturing supplement, to provide for a large-scale manufacturing site affiliated with the small-scale manufacturing site currently referenced in the approved NDA. In April 2020, the FDA requested that we include certain stability data in this planned prior approval manufacturing supplement, which we expect will result in a planned submission of this supplement in early 2021.

Financial Overview

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, nonclinical pharmacology studies, manufacturing process-development and scale-up activities, clinical trial and related clinical and pre-approval manufacturing expenses, fees paid to contract research organizations, or CROs, investigative sites, and other external expenses. In the early phases of development, our research and development costs included expanding our technology platform as well as early development of specific product candidates. The majority of our research and development expenses has been spent on the development of octreotide capsules, including the pre-approval manufacturing expenses, manufacturing of clinical trial material, manufacturing process development and validation, regulatory and clinical activities, and our TPE platform. Now that MYCAPSSA has been approved by the FDA, manufacturing costs related to the production of commercial supplies of MYCAPSSA will no longer be captured in R&D expense but will be capitalized to inventory. We expense research and development costs as incurred.

We have limited research and discovery functions and are currently not materially investing in those areas. We have focused our resources on the clinical development of octreotide capsules, including our two international Phase 3 trials, CHIASMA OPTIMAL and MPOWERED. Product candidates in late stages of development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of late-stage clinical trials. We plan to continue the open label extension portion of our international Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly. We also expect to continue to conduct our international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly to support potential regulatory approval in the European Union, as well as an open label extension of MPOWERED once the trial is completed. The successful development of octreotide capsules for commercialization outside the United States is highly uncertain.

General and Administrative

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, marketing, patient services, information technology and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses, travel expenses for our general and administrative personnel and professional fees for auditing, tax, and corporate, litigation and intellectual property-related legal services.

Marketing expenses consist of professional fees related to preparation for the commercialization of MYCAPSSA, as well as salaries and related benefits for commercial employees. Our marketing expenses for the six months ended June 30, 2019 were immaterial. Following the positive top-line data from our CHIASMA OPTIMAL trial, which we released in July 2019, we incurred pre-commercial marketing related expenses prior to FDA approval and we expect the commercial expenses to substantially increase as we commercialize MYCAPSSA in the United States following our FDA approval on June 26, 2020. In addition to anticipated future increases in marketing expenses, as we prepare for the potential commercialization of octreotide capsules and grow our operations, we have begun to incur additional other general and administrative expenses which we expect will continue to increase.

Interest and Other Income, Net

Interest and other income, net consists primarily of interest income earned on our investments.

Interest Expense

Interest expense consists primarily of interest expense associated with our Revenue Interest Financing Agreement.

Provision for Income Taxes

We are subject to federal and state income taxes for earnings generated in the United States, and foreign taxes on earnings of our wholly-owned Israeli subsidiary. Our consolidated tax expense is primarily affected by the mix of our foreign subsidiary permanent items, discrete items, and unrecognized tax benefits and to a lesser extent our taxable income (loss) in the United States.

Critical Accounting Policies and Use of Estimates

We have adopted various accounting policies to prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. Our most significant accounting policies are described in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. For information on accounting policies as well as new pronouncements adopted in the current period and recently issued standards, see Note 1 to our condensed consolidated financial statements. The preparation of our condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Our estimates and assumptions include those related to the accounting for stock-based compensation, income taxes, deferred royalty obligations, including embedded derivative liabilities, and accounting for certain accruals. We assess the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Results of Operations for the Three and Six Months ended June 30, 2020 and 2019

Research and Development

The following is a comparison of research and development expenses for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change	% Change	2020	2019	$ Change	% Change
	($ in thousands)							
Research and development	$9,672	$5,522	$4,150	75%	$17,797	$11,993	$5,804	48%

For the three months ended June 30, 2020, our total research and development expenses increased by $4.2 million to $9.7 million compared to the prior year period. For the six months ended June 30, 2020, our research and development expenses increased by $5.8 million compared to the prior year period. The increases for the three and six months ended June 30, 2020 as compared to the prior year periods were primarily due to an increase in manufacturing of octreotide capsules to support our planned U.S. commercial launch, costs associated with our disease state registry, scientific literature publications and increased regulatory costs which were offset by a decrease in clinical trial costs.

General and Administrative

The following is a comparison of general and administrative expenses for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change	% Change	2020	2019	$ Change	% Change
	($ in thousands)							
General and administrative	$10,665	$2,644	$8,021	303%	$18,247	$5,094	$13,153	258%

For the three months ended June 30, 2020, our general and administrative expenses increased by $8.0 million compared to the prior year period. The increase for the three months ended June 30, 2020 as compared to the prior year period was primarily due to our continuing pre-commercialization activities of $5.6 million, an increase in compensation-related expenses and increased other administrative costs as we prepare for commercialization of octreotide capsules. For the six months ended June 30, 2020, our general and administrative expenses increased by $13.2 million compared to the prior year period. The increase for the six months ended June 30, 2020 as compared to the prior year period was primarily due to our continuing pre-commercialization activities of $8.6 million, an increase in compensation-related expenses and increased other administrative costs as we prepare for commercialization of octreotide capsules.

Interest and Other Income, net

Interest and other income, net totaled $0.5 million for the six months ended June 30, 2020 compared to other income of $0.5 million for the same period in 2019. Our interest income was driven by the increase of our cash equivalents and marketable securities which were effectively offset by a decrease in the interest rate yield on our cash equivalents and marketable securities.

Interest Expense

Interest expense totaled $0.9 million for the six months ended June 30, 2020 primarily driven by interest expense related to our Revenue Interest Financing Arrangement which was entered into in April 2020.

Provision for Income Taxes

Our total tax provision was approximately $89,000 for the six months ended June 30, 2020, representing an effective tax rate of (0.2%), as compared to a tax provision of approximately $28,000 for the six months ended June 30, 2019, representing an effective tax rate of (0.2%).

Our effective tax rate differs from the statutory rate each year mainly due to a full valuation allowance maintained against U.S. deferred tax assets and due to lower tax rates applied to income of our Israeli subsidiary.

Liquidity and Capital Resources

In July 2015, we completed our IPO in which we raised $106.5 million by selling shares of common stock. In April 2019, we completed a follow-on public offering of common stock in which we raised an additional $32.2 million in net proceeds to finance our operations. In August 2019, we completed a follow-on public offering of common stock in which we raised an additional $52.3 million in net proceeds to finance our operations. In July 2020, we completed a follow-on public offering which consisted of common stock and pre-funded warrants in which we raised an additional $75.5 million in net proceeds to finance our operations. In April 2020, we entered into the Revenue Interest Financing Agreement with HCR for up to $75.0 million. The initial funding of $25.0 million, less certain transaction expenses, was completed in April 2020 and the second funding of $25.0 million, less certain transaction expenses, was completed in July 2020. The remaining $25.0 million of funding is contingent upon the achievement of certain milestones. Further, the Revenue Interest Financing Agreement requires us to maintain a minimum of $20.0 million in securitized cash and investment accounts during any quarter that the trailing four quarters of net revenue of MYCAPSSA is below a certain threshold. In April 2020, we also entered into the ATM Agreement with Jefferies, which allows us to offer and sell up to $60.0 million in gross proceeds of common stock from time to time, through Jefferies, acting as our sales agent or principal. To date, we have not sold any common stock under the ATM Agreement. As of June 30, 2020, our cash and cash equivalents were $52.2 million, of which $0.4 million was held by our Israeli subsidiary. In addition, as of June 30, 2020, we had $14.9 million invested in short-term marketable securities and $20.0 million of restricted cash.

Plan of Operations and Future Funding Requirements

We expect that our primary uses of capital will be associated with the commercialization of MYCAPSSA in the United States and the manufacturing of octreotide capsules for market consumption, seeking regulatory approval of octreotide capsules in the European Union, including clinical trial costs (including our international Phase 3 MPOWERED clinical trial to support regulatory approval of octreotide capsules in the European Union and its planned open label extension once completed, and our international Phase 3 CHIASMA OPTIMAL clinical trial open label extension), medical affairs activities, legal and regulatory expenses related to seeking regulatory approval of octreotide capsules in the European Union, compensation and related expenses, third-party clinical development services, and other general operating costs.

We currently expect our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations, as currently planned, through at least one year after the filing of this Quarterly Report. We cannot estimate the actual amounts necessary to successfully commercialize MYCAPSSA in the United States and complete the development and commercialization of octreotide capsules in the European Union, if at all, or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including, but not limited to:

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for octreotide capsules and any other future product candidates for which we receive marketing approval;
- proceeds, if any, received from commercial sales of octreotide capsules and any future product candidates for which we receive marketing approval;
- the costs, timing and outcome of the development and regulatory review of octreotide capsules and our CBE-30 supplement and planned prior approval manufacturing supplement;
- the progress and results of our ongoing clinical trials of octreotide capsules or any future clinical trials or studies we may conduct;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we develop, acquire or in-license other product candidates and technologies or explore or consummate other strategic transactions.

We filed a $200.0 million shelf registration statement on Form S-3 with the SEC in September 2019, which the SEC declared effective in September 2019. In April 2020, we entered into the ATM Agreement with Jefferies, under which we may offer and sell from time to time shares of our common stock having an aggregate offering price of up to $60.0 million through Jefferies, acting as our sales agent or principal. To date, we have not sold any shares of common stock under the ATM Agreement. In July 2020, we completed a follow-on public offering which consisted of common stock and pre-funded warrants, in which we raised $80.5 million in gross proceeds, or $75.5 million net proceeds less underwriting fees and offering expenses.

To the extent that we raise additional capital through future issuance of equity or convertible debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration or other financing arrangements, we may have to relinquish valuable rights to our current or future product candidates, exploratory programs, technologies or future revenue streams on terms that may not be favorable to us. If we are unable to raise additional funds through equity or other financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts of octreotide capsules or grant rights to develop and market future potential product candidates that we would otherwise prefer to develop and market ourselves.

Revenue Interest Financing Agreement

In April 2020, we entered into a Revenue Interest Financing Agreement with HCR whereby HCR will receive payments from us at a tiered percentage, or the Applicable Tiered Percentage, of future net revenues of MYCAPSSA and any of our other future products, including worldwide net product sales and upfront payments, and milestones, collectively, the Revenue Interests. Under the terms of the agreement, we received $25.0 million, less certain transaction expenses, from HCR in April 2020 and received an additional $25.0 million following the FDA approval of MYCAPSSA in July 2020 , and are entitled to receive an additional $15.0 million upon certain conditions related to commercial drug supply availability and first commercial sale of MYCAPSSA, subject to customary closing conditions, which we expect to receive in the second half of 2020. We are also entitled to receive an additional $10.0 million in early 2022 subject to the achievement of a revenue milestone and customary closing conditions. In exchange for the total investment amount, or

Investment Amount, received, HCR will receive a tiered royalty in the low double digits on worldwide annual net revenues of MYCAPSSA and any other future products, subject to step-downs upon the achievement of certain annual revenues.

HCR's rights to receive the Revenue Interests shall terminate on the date on which HCR has received payments equal to 195% of the funded portion of the Investment Amount including the aggregate of all payments made to HCR as of such date, unless the Revenue Interest Financing Agreement is earlier terminated. If HCR has not received payments equal to the 195% of the funded portion of the Investment Amount by the ten-year anniversary of the initial closing date and no event of default has occurred or is ongoing, among other things, we shall pay HCR an amount equal to the funded portion of the Investment Amount plus a specific annual rate of return in the low to mid-teens less payments previously received. If a change of control of the Company occurs, we must immediately repay HCR the total amount actually funded, including any amount conditionally eligible to be funded, plus a change of control premium, the amount of which is variable up to 95% based on timing and circumstances of such change of control and the amount funded and conditionally eligible to be funded by HCR as of the date of the change of control. Upon the occurrence of an event of default, including the withdrawal, suspension or other termination of the FDA approval of MYCAPSSA as a treatment for acromegaly that continues for sixty days that prevents us from marketing MYCAPSSA, HCR may accelerate payments due under the agreement to the 195% of the funded portion of the Investment Amount.

If HCR has not received 60% of the Investment Amount by September 30, 2023 or 100% of the Investment Amount by September 30, 2024, we must make cash payments sufficient to gross HCR up to such minimum amounts. Further, the Revenue Interest Financing Agreement requires us to maintain a minimum of $20.0 million in securitized cash and investment accounts during any quarter that the trailing four quarters of net revenue of MYCAPSSA is below a certain threshold. Our obligations under the Revenue Interest Financing Agreement are secured by a first priority perfected security interest in all of our cash and cash equivalents (as defined in the Revenue Interest Financing Agreement), all present and future net revenues of MYCAPSSA and all MYCAPSSA-related assets.

Cash Flows

The following is a summary of cash flows for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	($ in thousands)	
Cash flows provided by (used in):		
Operating activities	$(28,952)	$(16,108)
Investing activities	49,354	(8,646)
Financing activities	23,937	32,262

Operating Activities

Net cash used in operating activities was $29.0 million for the six months ended June 30, 2020, and primarily consisted of $36.5 million in net loss, adjusted for non-cash items of $2.7 million (primarily stock-based compensation) and working capital increase of $4.8 million (primarily due to the increase in accounts payable and accrued expenses offset by decreases in prepaid expenses and other assets). Net cash used in operating activities was $16.1 million for the six months ended June 30, 2019, and primarily consisted of $16.6 million in net loss, adjusted for non-cash items of $1.1 million (primarily stock-based compensation) and working capital decrease of $0.6 million (primarily due to the decrease in accounts payable and accrued expenses and partially offset by the decrease in prepaid expenses and other current assets). The primary driver for the increase in our cash used in our operating activities during the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was the manufacturing and pre-commercial costs incurred as we prepared for the commercialization of octreotide capsules.

Investing Activities

Net cash provided by investing activities was $49.4 million for the six months ended June 30, 2020, primarily related to the net maturities of marketable securities, compared to $8.6 million in cash used in investing activities for the six months ended June 30, 2019, primarily related to the net purchases of marketable securities driven by the net proceeds received from our follow-on public offering in April 2019.

Financing Activities

Net cash provided by financing activities was $23.9 million during the six months ended June 30, 2020, primarily related to the net proceeds from the Revenue Interest Agreement with HCR in April 2020. For the six months ended June 30, 2019, net cash provided by financing activities was $32.3 million, primarily related to the net proceeds received from our follow-on public offering in April 2019.

Contractual Obligations

As of June 30, 2020, we had outstanding manufacturing commitments, including the acquisition of API, in the aggregate amount of $25.2 million of which $9.2 million is expected to be incurred in 2020 with the remainder to be incurred throughout 2021. The payments on these commitments will occur following the deliveries of the API or completion of the manufacturing services. As of June 30, 2020, we had future minimum lease payments under non-cancelable operating leases in the aggregate amount of $1.6 million.

As of April 7, 2020, we have contractual obligations under the Revenue Interest Financing Agreement with HCR, as noted above and disclosed in Note 6 included under Part I, Item 1 of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2020, we had $72.2 million in cash, cash equivalents and restricted cash, consisting of cash in checking accounts at U.S. and Israeli banking institutions as well as money market funds. In addition, as of June 30, 2020, we had $14.9 million of marketable securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point increase in interest rates would cause a decrease in the value of our short-term investments of approximately $28,000. As of June 30, 2020, we did not have any outstanding variable interest rate borrowings, and as a result we are not exposed to interest rate risk associated with credit facilities.

In addition, we are subject to currency risk for balances held, or denominated, in currencies other than U.S. dollars. We work to maintain all balances in U.S. dollars until payment in other currencies is required to minimize this currency risk. Fluctuations in the exchange rate between the U.S. dollar and each of the Euro, GBP and NIS over the past 24 months have been approximately (4%), (7%), and 5%, respectively. As of June 30, 2020, we held $0.4 million in Israeli banks and petty cash funds to support our Israeli operations, the majority of which is denominated in U.S. dollars. We contract with CROs internationally, primarily for the execution of clinical trials and manufacturing activities. Transactions with these providers are settled in U.S. dollars, Euros or GBP and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not currently hedge against foreign currency exchange rate risks.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and

reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2020, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

As of the date of this filing, we were not party to any legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 16, 2020.*

Risks Related to the Development and Potential Regulatory Approval and Commercialization of Octreotide Capsules and any Future Product Candidates

We are substantially dependent on the successful commercialization of MYCAPSSA, which received approval from the FDA in June 2020. If we are unable to successfully commercialize MYCAPSSA in the United States, including securing and maintaining regulatory approval necessary for distribution of commercial product, and obtain regulatory approval and successfully commercialize octreotide capsules in the European Union, or if we are substantially delayed in doing so, our business may be materially harmed.

On June 26, 2020, the FDA granted approval of oral octreotide capsules, MYCAPSSA®, for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide, which is our only regulatory approval of a product. MYCAPSSA is our only product that has been approved for sale by the FDA. We have not yet begun to commercialize MYCAPSSA and the commercial launch of MYCAPSSA is not expected to commence until the fourth quarter of 2020. We have invested a significant portion of our activities and resources toward the development of MYCAPSSA, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize MYCAPSSA in the United States.

Our NDA that was approved by the FDA in June 2020 references one small-scale manufacturing site for the active pharmaceutical ingredient, or API, in octreotide owned by our planned secondary commercial API manufacturer. However, we have not procured commercial API from this manufacturing site for our planned commercial launch. Accordingly, in order to commercially launch octreotide capsules, on June 29, 2020, we submitted to the FDA a manufacturing supplement to the NDA as a "changes being effected in 30 days" supplement, or CBE-30 supplement, to provide for the approval of our primary API manufacturer and one of its large-scale manufacturing sites. If the FDA accepts the CBE-30 supplement without delay or exception, we expect to begin distributing commercial product as part of our U.S. commercial launch as soon as we have supplies of MYCAPSSA available at our third-party logistics provider, which we expect by the end of the third quarter of 2020 while the FDA's review of the CBE-30 supplement is pending. In addition, we also plan to file a second manufacturing supplement to the NDA, which we expect will be a prior approval manufacturing supplement, to provide for a large-scale manufacturing site affiliated with the small-scale manufacturing site currently referenced in the approved NDA. In April 2020, the FDA requested that we include certain stability data in this planned prior approval manufacturing supplement, which we expect will result in a planned submission of this supplement in early 2021. If we are unable to obtain the FDA's approval of our CBE-30 supplement or our planned second manufacturing supplement in a timely manner or at all, our planned commercial launch could be negatively impacted. The review of any manufacturing supplement to the NDA will require FDA review and approval of the manufacturing process, facility, equipment and procedures in place at each manufacturing site, including batch-to-batch comparability and API and drug product stability data, in accordance with the FDA's cGMP requirements and may require regulatory inspections of each manufacturing site, which could prevent or delay approval of any such manufacturing supplement and prevent or delay our planned commercial launch. If the FDA determines during its review process that it has significant substantive issues with our CBE-30 supplement, it could require us to cease or restrict our distribution of oral octreotide in the United States or potentially recall distributed drug product. The timing of the FDA's review process related to our CBE-30 supplement and planned second manufacturing supplement and the outcome of such reviews are inherently uncertain, and we can provide no assurances that either manufacturing supplement will be approved in a timely manner or at all.

Successful commercialization of MYCAPSSA is subject to many risks. We have never, as an organization, launched or commercialized a product, and there is no guarantee that we will be able to do so successfully with MYCAPSSA for its approved indication. There are numerous examples of other companies that have experienced unsuccessful product launches and failed to meet high expectations of market potential, including pharmaceutical companies with significantly more experience and resources than us.

The future success of MYCAPSSA, including the expected timing of the commercial launch, and the rate and degree of market acceptance, of MYCAPSSA in the United States, will depend on a number of factors, including:

- the efficacy and safety of MYCAPSSA in a larger number of patients in a non-clinical setting than those demonstrated in our clinical trials;
- our ability to manufacture sufficient commercial supplies of MYCAPSSA in compliance with regulatory requirements;
- the effectiveness of our sales, marketing and distribution efforts, particularly during the remote, COVID-19 environment;
- the incidence and prevalence of acromegaly patients in the U.S. that respond to and tolerate treatment with octreotide or lanreotide;
- the timing of market introduction of MYCAPSSA;

- the ability of MYCAPSSA to successfully compete against other products; acceptance by the medical community and patients of MYCAPSSA as a safe and effective product;
- the potential and perceived advantages of MYCAPSSA over alternative products;
- the ability to distinguish safety and efficacy from existing alternatives;
- the willingness of medical professionals to prescribe and patients to use MYCAPSSA and continue to use MYCAPSSA instead of alternative products;
- the prevalence and severity of adverse side effects;
- the convenience of prescribing, administrating and initiating patients on MYCAPSSA;
- the potential and perceived value and relative cost of MYCAPSSA over alternative products, including generic products or treatments;
- the availability of coverage and adequate reimbursement and pricing by private and government payors;
- the successful completion of any clinical trials, regulatory approval and commercialization of MYCAPSSA for one or more label expansion indications; and
- our ability to enforce our intellectual property rights with respect to MYCAPSSA.

While we have implemented our commercial launch readiness plans, we will need to incur significant additional expenses and commit significant additional management time to further develop our commercialization capabilities and to continue hiring, developing and training our sales force in order to be prepared to successfully coordinate the launch and commercialization of MYCAPSSA in the United States. We may not be able to successfully establish these capabilities on our expected timing or at all. Even if we are successful in building out our commercial team and sales force, there are many factors that could cause the launch and commercialization of MYCAPSSA to be unsuccessful and/or delayed, including a number of factors that are outside our control.

The commercial success of MYCAPSSA depends on the extent to which medical professionals and patients accept and adopt MYCAPSSA as a product for the for the treatment of acromegaly, and we do not know whether our or others' revenue estimates in this regard will be accurate. For example, if the patient population suffering from acromegaly is smaller than we estimate or if medical professionals are unwilling to prescribe or patients are unwilling to try and then continue to use MYCAPSSA, the commercial potential of MYCAPSSA will be limited. We also do not know how medical professionals, patients and third-party payors will respond to the pricing of MYCAPSSA. Medical professionals may not prescribe MYCAPSSA and patients may be unwilling to use MYCAPSSA if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost, and we may find it necessary or desirable to provide rebates on MYCAPSSA to customers or third-party payors or to expand existing, or implement new or additional, patient assistance programs, including co-pay assistance programs, which could materially adversely affect our profitability.

While the FDA granted approval of MYCAPSSA based on the data included in the NDA, we do not know whether the results when a larger number of patients are exposed to MYCAPSSA, including results related to safety and efficacy, will be consistent with the results from our clinical studies of MYCAPSSA that served as the basis of FDA approval of MYCAPSSA. New data relating to MYCAPSSA, including from any adverse event reports or any negative results during our MPOWERED trial or clinical development for additional indications of oral octreotide capsules, may adversely impact the commercial results and potential of MYCAPSSA. Thus, significant uncertainty remains regarding the commercial potential success of MYCAPSSA. In addition, such new data or any serious or unexpected side effects caused by MYCAPSSA may result in a number of potentially significant negative consequences, including:

- the FDA could withdraw its approval of MYCAPSSA, impose restrictions on its distribution or require the addition of labeling warnings or restrictions;
- we could be required to change the way MYCAPSSA is promoted or administered or conduct additional clinical studies;
- we could be sued and held liable for any harm caused to patients; or
- our reputation may suffer.

If the launch or commercialization of MYCAPSSA is delayed, unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be materially harmed.

While the FDA granted approval of MYCAPSSA, such approval does not guarantee FDA approval for any future product candidates. FDA approval of MYCAPSSA also does not guarantee that MYCAPSSA will be approved by the FDA for additional indications or by regulatory entities in countries outside of the United States.

See "Risk Factors—Risks Related to the Development and Potential Regulatory Approval and Commercialization of Octreotide Capsules and any Future Product Candidates" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which is incorporated by reference in this prospectus supplement, for a more detailed discussion of the risks related to the manufacturing, commercialization and ongoing regulation of drug products.

If we are unable to obtain regulatory approval and successfully commercialize octreotide capsules in the European Union, or if we are substantially delayed in doing so, our business may be materially harmed.

In October 2015, the European Medicines Agency, or EMA, accepted the design, enrollment criteria and required duration of our second Phase 3 trial to evaluate the non-inferiority of octreotide capsules to injectable somatostatin analogs in adult patients with acromegaly. This clinical trial, which is referred to as MPOWERED and was initiated in March 2016, is a global, randomized, open-label and active-controlled 15-month trial initially designed to enroll up to 150 patients in Europe, Russia, the United States and certain other countries. This clinical trial is currently designed to show comparative effectiveness as required by the EMA, to support submission of an MAA and potential approval. Our ongoing MPOWERED Phase 3 clinical trial may not be successful, or acceptable to the EMA to support regulatory approval in the European Union.

Importantly, the safety data generated in our completed clinical trials of octreotide capsules, including our first Phase 3 clinical trial and the CHIASMA OPTIMAL clinical trial as well as certain safety data from the MPOWERED clinical trial, as well as the efficacy data from our completed first Phase 3 clinical trial and the CHIASMA OPTIMAL trial, were integrated into the NDA that was approved by the FDA. We expect the safety and efficacy data from all three of our Phase 3 clinical trials to be submitted in our planned MAA filing. While the MPOWERED trial design has been accepted by the EMA, our ultimate success in the regulatory review process of our planned application for marketing approval in the European Union could be negatively impacted by the results from any of our clinical trials.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and these regulations differ from country to country and change over time. While we have obtained marketing approval for octreotide capsules in the United States, we are not permitted to market octreotide capsules in the European Union or any other countries outside the United States until we receive the requisite approvals in such countries. In the United States, the FDA generally requires the completion of nonclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality and other factors before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements and may impose pricing restrictions. Of the large number of drugs in development, only a small percentage result in the submission of an application for marketing authorization and even fewer are approved for commercialization.

Other than the June 2015 submission of our NDA for octreotide capsules as a treatment for acromegaly to the FDA and the December 2019 resubmission of our NDA, we have not yet submitted comparable applications to other regulatory authorities. If our development efforts for octreotide capsules, including our ability to obtain EMA regulatory approval, are not successful for the acromegaly indication or are delayed, if we are unsuccessful or delayed in obtaining regulatory approval of the CBE-30 supplement and planned manufacturing supplement to our NDA or if adequate demand for octreotide capsules are not generated, our business and ability to generate revenues will be materially harmed. Failure to obtain regulatory approval of the CBE-30 supplement and planned manufacturing supplement will prevent us from commercializing the product candidate in a timely manner or at all, which could raise significant concerns about our continued viability as a business. The success of octreotide capsules will depend on the receipt of additional regulatory approvals the issuance of such approvals is uncertain and subject to a number of risks, including the following:

- foreign regulatory authorities, institutional review boards, or IRBs, or ethics committees may disagree with the design or conduct of our clinical trials;
- the results of our clinical trials may not provide acceptable evidence of octreotide capsules' safety and efficacy;
- the results of our clinical trials may not be sufficiently robust or meet the level of statistical or clinical significance required by, the EMA or other regulatory agencies for marketing approval;
- the dosing of octreotide capsules in a particular clinical trial may not be at an optimal level;

- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to octreotide capsules;
- the data collected from our clinical trials may not be sufficient to obtain regulatory approval in the European Union or elsewhere; and
- even if we obtain marketing approval in one or more countries, future safety or other issues could result in the suspension or withdrawal of regulatory approval in such countries.

In particular, we cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted to date, as was the case with the FDA's review of our completed first Phase 3 clinical trial contained in the original NDA, or that any current or future trials will be successful. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional clinical trials, or nonclinical or other studies, as the FDA strongly recommended in its Complete Response Letter to our NDA that we received in April 2016, or the CRL. We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied before, and expect to continue to rely, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application or may result in future withdrawal of approval. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction.

Our development, regulatory and commercialization strategy for octreotide capsules continues to depend, in part, on published scientific literature and prior findings regarding the safety and efficacy of approved products containing octreotide.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or Section 505(b)(2). Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person or entity by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any difference from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the listed drug has been approved, as well as for any new indication(s) sought by the Section 505(b)(2) applicant as supported by additional data. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the listed drug's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions.

We designed our nonclinical and clinical programs to seek regulatory approval for octreotide capsules for registration filing in the United States using the FDA's 505(b)(2) regulatory pathway and using the hybrid application pathway in the European Union. Our NDA for which we received FDA approval of octreotide capsules as a treatment for acromegaly relied, and we intend that our planned MAA will rely, in part, on previous findings of safety and efficacy for an approved immediate-release injectable octreotide product and published scientific literature for which we have not received a right of reference. Even though we designed our development programs to take advantage of Section 505(b)(2) and the hybrid application pathway to support potential regulatory approval of octreotide capsules in the United States and the European Union and obtained FDA approval of our NDA for octreotide capsules as a treatment for acromegaly, if the MPOWERED trial is successful and we submit an MAA to the EMA, the EMA may require us to perform additional clinical trials or measurements to support approval over and above the clinical trials that we have already completed or initiated. The EMA also may determine that we have not provided sufficient data to justify reliance on prior investigations involving the approved immediate-release injectable octreotide product.

In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), in the past some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). For example, parties have filed citizen petitions objecting to the FDA approving a Section 505(b)(2) NDA on scientific, legal and

regulatory grounds. Scientific arguments have included the assertions that for the FDA to determine the similarity of the drug in the 505(b)(2) NDA to the listed drug, the FDA would need to reference proprietary manufacturing information or trade secrets in the listed drug's NDA; that it would be scientifically inappropriate for the FDA to rely on public or nonpublic information about the listed drug because it differs in various ways from the drug in the 505(b)(2) NDA; or that differences between the listed drug and the drug in the 505(b)(2) NDA may impair the latter's safety and effectiveness. Legal and regulatory arguments have included the assertion that Section 505(b)(2) NDAs must contain a full report of investigations conducted on the drug proposed for approval, and that approving a drug through the 505(b)(2) regulatory pathway would lower the approval standards. In addition, citizen petitions have made patent-based challenges against 505(b)(2) NDAs. For example, petitioners have asserted that the FDA should refuse to file a 505(b)(2) NDA unless it references a specific NDA as the listed drug, because it is "most similar" to the proposed drug, and provides appropriate patent certification to all patents listed for that NDA; or that when a 505(b)(2) NDA is pending before the FDA, but before it is approved, where the FDA approves an NDA for a drug that is pharmaceutically equivalent to the drug that is the subject of the 505(b)(2) NDA, then the FDA should require that the 505(b)(2) NDA be resubmitted referencing the approved NDA as the listed drug and certifying to the listed patents for that approved drug. However, if the FDA or EMA changes its interpretation of Section 505(b)(2) or the hybrid application pathway, or if the FDA's or EMA's interpretation is successfully challenged in court, this could delay or even prevent the FDA or EMA, as applicable, from approving any Section 505(b)(2) NDAs or hybrid application pathway MAAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of octreotide capsules for the treatment of acromegaly or any future product candidates we may develop.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and our current and future clinical trials may not be successful. Results of earlier studies and trials may not be predictive of future trial results, and approval in one jurisdiction may not be predictive of approval in other jurisdictions.

Conducting clinical trials and developing drugs is a lengthy, time consuming and expensive process. For example, we incurred significant expenses in developing and obtaining the FDA's approval of octreotide capsules for the treatment of acromegaly with no guarantees that doing so would result in such an approval and we expect to continue to incur significant expenses for our Phase 3 clinical trial of octreotide capsules in acromegaly called MPOWERED to support potential regulatory approval in the European Union and our planned MAA to the EMA if the MPOWERED trial is successful. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain, and we will continue to be subject to these risks. Failure can occur at any time during the clinical trial process and results of past, current or future trials, such as the MPOWERED trial, can adversely affect prospects of securing regulatory approval or regulatory approvals previously received.

The results of nonclinical studies and prior clinical trials may not be predictive of the results of future clinical trials. The results of our completed clinical trials for octreotide capsules in acromegaly, including the CHIASMA OPTIMAL Phase 3 trial, do not ensure that future clinical trials, including the MPOWERED Phase 3 trial designed to support EMA approval, will also generate comparable results. Among other considerations, these trials may be designed in a way that is different from our completed clinical trials. For example, the EMA required that we use multiple time points in the Phase 3 clinical trial that we initiated in March 2016 rather than a single time point for the primary endpoint determination used for our initial Phase 3 clinical trial. While the EMA agreed that we use the same cut off as used in our first Phase 3 clinical trial of IGF-1 < 1.3 times the upper limit of normal as the threshold for response, the FDA agreed that we use IGF-1 £ 1.0 times the upper limit of normal in the CHIASMA OPTIMAL trial. The fact that we have not used such endpoints previously for regulatory submissions outside the United States introduces an additional level of uncertainty in the outcome of the MPOWERED Phase 3 clinical trial, and the ability for the data from that trial to support regulatory approval from the EMA. We cannot provide assurance that the FDA or EMA will view the results as we do or that any of our ongoing or future trials of octreotide capsules, including our MPOWERED Phase 3 clinical trial in acromegaly, or any clinical trials we may conduct for other indications, if any, will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and prior clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in prior trials.

Despite the results reported in earlier nonclinical studies and clinical trials for octreotide capsules for the treatment of acromegaly, any current or future clinical trial results of octreotide capsules may not be successful in acromegaly, or any other indication, if studied. A number of factors could contribute to a lack of favorable safety and efficacy results for octreotide capsules for acromegaly or other indications. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period, and varying patient characteristics, including demographic factors and health status. If later-stage clinical trials, such as MPOWERED, do not produce favorable results, it will raise substantial doubt about our ability to achieve regulatory approval of octreotide capsules for the treatment of acromegaly or other indications.

Further, our resubmitted NDA for which we obtained FDA approval relied upon the FDA's 505(b)(2) regulatory pathway for octreotide capsules in acromegaly in the United States and we expect to rely on a similar hybrid application pathway for the MAA that we plan to submit in the European Union. There can be no assurance that our clinical trials, or the clinical trials conducted by third parties, will demonstrate sufficient safety and efficacy for the EMA to approve octreotide capsules for the treatment of acromegaly or for the FDA or EMA to approve octreotide capsules for any other indication that may be specified in future NDA or MAA submissions. Even though we did obtain approval from the FDA for octreotide capsules for the treatment of acromegaly in the United States, we may not be successful in obtaining approval from the EMA or other regulatory authorities.

Any negative clinical results from, termination or suspension of, or delays in the commencement or completion of any ongoing or future trials of octreotide capsules for the treatment of acromegaly or for any additional indications, in the United States or other countries, or future clinical trials of product candidates we may develop could result in increased costs to us, delay or limit our ability to generate revenue or achieve or sustain profitability, negatively impact our commercial prospects, cause our market value and stock price to fall and jeopardize our viability as a business.

Delays in the completion of the Phase 3 MPOWERED clinical trial we initiated in March 2016 to support marketing approval of octreotide capsules as a treatment for acromegaly in the European Union, the clinical trials of octreotide capsules for other indications we may pursue, if conducted, or any future clinical trials we may conduct for other product candidates we may develop, or negative findings in those trials, could significantly increase our product development costs and jeopardize our ability to commercialize octreotide capsules. For example, if the topline data from the Phase 3 MPOWERED clinical trial, which we expect to report in the fourth quarter of 2020, are negative, those data could negatively impact the commercial prospects for octreotide capsules in the United States.

Furthermore, in October 2015, the EMA required us to revise our protocol for our MPOWERED Phase 3 clinical trial to extend the control period from six months to nine months. The final protocol accepted by EMA therefore dictated that additional time will be needed to complete our second Phase 3 clinical trial of octreotide capsules. While enrollment and randomization are complete, we do not know whether the MPOWERED Phase 3 trial will be completed on schedule or will be successful. In light of the FDA's position that the MPOWERED clinical trial would not be sufficient to address the concerns in the CRL, in late 2016 we modified certain elements of the MPOWERED trial in an effort to preserve patients, sites and other resources that were necessary to conduct the CHIASMA OPTIMAL Phase 3 trial. The modifications to the MPOWERED trial, together with our decision in October 2018 to enroll up to 15 additional patients, delayed the expected timing of an MAA submission with the EMA. We now expect top-line data from the MPOWERED study in the fourth quarter of 2020. The completion of the MPOWERED Phase 3 trial or other clinical trials we may conduct could be delayed for a number of other reasons, including delays related to:

- the FDA, the EMA or any other relevant regulatory authority failing to grant permission to proceed and placing the clinical trial on hold;
- patient enrollment and variability in the number and types of patients available for clinical trials, which is particularly challenging for orphan indications, including due to other ongoing clinical trials in the same or similar disease state;
- a facility manufacturing octreotide acetate, octreotide capsules, placebo capsules or any other product candidate we may develop being found deficient in its processes, as the FDA noted in the CRL and as was observed in a recent regulatory inspection at the time of our NDA resubmission, or ordered by the FDA, EMA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired or a failure to successfully manufacture qualifying clinical trial supplies of oral octreotide capsules or placebo;
- patients choosing an alternative treatment for acromegaly or any of the indications for which we may develop octreotide capsules or potential product candidates, or participating in competing clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete or missing data;
- patients experiencing drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;

- third-party clinical investigators losing their licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods that are inconsistent with the clinical trial protocol, good clinical practice, or GCP, requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA, EMA or other regulatory authorities finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs or ethics committees refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional patients, or withdrawing its approval of the trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- delays in adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason;
- the inability to enroll patients who participated in prior clinical trials in our current or planned clinical trials; or
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for octreotide capsules in acromegaly or any other future indications we may pursue or for product candidates we may develop in the future will increase if we have delays in testing or approval, such as the delay in approval of octreotide capsules that we experienced due to the CRL, or if we need to perform more or larger clinical studies than planned. If we experience delays in the completion of, or if we, the FDA, other regulatory authorities, IRBs or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials of octreotide capsules for any indication or for product candidates we may develop in the future, its commercial prospects may be harmed and our ability to generate product revenues or achieve or sustain profitability will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial or even withdrawal of regulatory approval of octreotide capsules for any indication or for product candidates we may develop in the future. In addition, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of octreotide capsules could be significantly reduced.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA’s and other regulatory authorities’ policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of octreotide capsules and any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would harm our business, prospects, financial condition and results of operations.

If we are required to conduct additional clinical trials or other studies with respect to octreotide capsules or any future product candidates we may develop beyond those that we may propose to conduct, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of octreotide capsules and any future product candidates we may develop, we may not be able to obtain regulatory approval at all or we may

obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for octreotide capsules or any future product candidates we may develop. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

**** Changes in funding for, or leadership at, or disruptions at the FDA, the SEC and other government agencies, including due to the novel coronavirus COVID-19 pandemic, could hinder their ability to hire and retain key personnel, prevent new products and services from being developed, approved or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including prioritization of activities related to managing the novel coronavirus COVID-19 pandemic, government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, the FDA and other government agencies on which our business relies is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, the FDA is experiencing disruptions related to the novel coronavirus COVID-19 pandemic, including postponing most foreign inspections and scaling back domestic inspections, and has also warned that it may be unable to sustain its current level of performance for its new drug program and other programs. If a prolonged government shutdown or other disruption occurs or if disruptions related to the outbreak of novel coronavirus COVID-19 pandemic continue or worsen, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown or other disruption could prevent the timely review of patent applications by the United States Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may find it difficult to enroll patients in our clinical trials, in particular with respect to octreotide capsules and any other product candidates that we may pursue, which could delay or prevent clinical trials of octreotide capsules and any future product candidates we may develop and potentially harm our business.

Identifying and qualifying patients to participate in clinical trials of octreotide capsules and any future product candidates we may develop is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing octreotide capsules and any future product candidates we may develop as well as completion of required follow-up periods. If patients are unable or unwilling to participate in our clinical trials for any reason, including if patients choose to enroll in competitive clinical trials for similar patient populations or they are unwilling to enroll and stay in a clinical trial with a placebo-controlled design, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of octreotide capsules and any future product candidates we may develop may be delayed. These delays could result in increased costs, and we may not have sufficient capital on hand or the ability to raise additional capital to cover such costs, delays in advancing octreotide capsules or any future product candidates we may develop, delays in testing the effectiveness of future product candidates, if any, or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. In particular, the conditions for which we may evaluate octreotide capsules are orphan diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. For example, while we were enrolling patients in the United States, Russia, Europe and other countries, we were not permitted to enroll patients from our prior clinical trials in our ongoing MPOWERED Phase 3 clinical trial to support MAA submission and approval in the European Union. The same limitation was true for our CHIASMA OPTIMAL trial. Further, in light of the FDA's position that the MPOWERED clinical trial would not be sufficient to address the concerns in the CRL, we modified certain elements of the MPOWERED trial in an effort to preserve patients, sites and other resources necessary to conduct the CHIASMA OPTIMAL Phase 3 trial.

Patient enrollment is affected by factors including the:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- perceived risks and benefits of the product candidate under trial;
- possibility of receiving placebo rather than active drug in certain controlled trials, such as was the case in the CHIASMA OPTIMAL trial;
- eligibility criteria for the trial in question;
- possibility of being randomized back to current injectable therapies, such as in the MPOWERED trial, or rescued back to current injectable therapies following a loss of biochemical and symptom control, such as was the case in the CHIASMA OPTIMAL trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- perceptions of patients and healthcare providers as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment of patients in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials or our clinical trials produce incomplete data, we may be forced to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of octreotide capsules and any future product candidates that we may develop in lieu of prescribing existing treatments that have established safety and efficacy profiles. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA, the EMA or other regulatory authorities. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including the:

- difficulty in establishing or managing relationships with CROs and physicians;
- different requirements and standards for conducting clinical trials;
- inability to locate qualified local consultants, physicians and partners; and
- potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

**** Even though we received FDA approval of our NDA for octreotide capsules as a treatment for acromegaly, we must also obtain regulatory approval of our CBE-30 supplement or our other planned manufacturing supplement and may still face additional future development and regulatory challenges, each of which could inhibit or preclude our ability to commercialize octreotide capsules for any indication.***

In order to have octreotide capsules available for our planned commercial launch in the fourth quarter of 2020, the FDA must accept our CBE-30 supplement to our approved NDA in a timely manner. If the FDA accepts the CBE-30 supplement without exception or delay, we expect to distribute commercial product as part of our U.S. commercial launch while the FDA's review of the supplement is pending. However, if the FDA determines during its review process that it has significant substantive issues with our CBE-30 supplement it could require us to cease or restrict our distribution of oral octreotide in the United States or potentially recall distributed drug product. In addition, we also plan to file a second manufacturing supplement to the NDA, which we expect will be a prior approval manufacturing supplement, to provide for a large-scale manufacturing site affiliated with the small-scale manufacturing site currently referenced in the NDA. If we are unable to obtain or are delayed in obtaining regulatory approval of our CBE-30 supplement or planned second manufacturing supplement, our planned commercial launch could be negatively impacted.

Further, even though we obtained FDA approval of our NDA for octreotide capsules as a treatment of acromegaly and even if we obtain additional regulatory approvals for octreotide capsules as a treatment for acromegaly or for other indications we may pursue, or any other product candidates we may develop, they remain subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of octreotide capsules and any future product candidates we may develop will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If new safety information becomes available after approval of octreotide capsules and any future product candidates we may develop, the FDA or comparable foreign regulatory authorities may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy, impose significant restrictions on our product candidates, indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for octreotide capsules, includes some restrictions on use, which could limit the marketability of octreotide capsules and impair our ability to have octreotide capsules gain market acceptance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and other regulations. The third-party contract manufacturers that we utilize or plan to utilize for commercial supply have been subject to ongoing regulatory inspections from time to time that resulted in inspectional observations. For example, in the CRL, the FDA advised that, during a site inspection, certain deficiencies were conveyed to the representative of one of our suppliers. In addition, in connection with the resubmission of our NDA, we did not reference in the NDA resubmission our planned primary commercial API manufacturer due to unresolved observations from a recent regulatory inspection. If we or a regulatory authority discover any new or previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or with any facility where the product is manufactured, we may recall or withdraw the product from the market or a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring suspension of manufacturing. If we, our potential products or the manufacturing facilities for our potential products fail to comply with applicable regulatory requirements, a regulatory authority may, among other things:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize octreotide capsules and any future product candidates we may develop and generate revenue.

We face substantial competition from larger companies with considerable resources that already have somatostatin analogs available in the market, and they or others may also discover, develop or commercialize additional products before or more successfully than we do.

Our industry is highly competitive and subject to rapid and significant technological change as researchers learn more about diseases and develop new technologies and treatments. Our potential competitors include primarily large pharmaceutical, biotechnology and specialty pharmaceutical companies. We expect octreotide capsules will face competition from established drugs and major brand names and also generic versions of these products. Key competitive factors affecting the commercial success of octreotide capsules and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement and effectiveness of our promotional activities. For example, physicians may choose not to prescribe octreotide capsules

because a lower percentage of patients met the criteria for response in our first Phase 3 clinical trial after treatment with octreotide capsules compared to their baseline response rates on injectable therapy, similar data was produced in the CHIASMA OPTIMAL trial, or may also occur in the MPOWERED clinical trial. Competition could also force us to lower prices or could result in reduced sales.

The standards of care for patients suffering from acromegaly all involve injectable therapies, other than cabergoline, an oral agent used for the treatment of mild acromegaly. Novartis markets octreotide LAR, which is administered monthly and intramuscularly using a large gauge needle. Ipsen markets lanreotide, another long-acting analog of somatostatin, like octreotide, which is administered monthly using a deep subcutaneous injection. Recordati markets pasireotide LAR, which is another somatostatin analog administered via intramuscular injection. Our FDA-approved product label for MYCAPSSA is only indicated for acromegaly patients who have responded to and tolerated treatment with octreotide and lanreotide. Pfizer markets pegvisomant daily injections, which is a growth hormone receptor antagonist. Generic versions of these drugs may also bring additional competition to the treatment landscape. For example, while octreotide LAR and lanreotide currently have no generic competitors in the United States, generic versions are available in some markets in the European Union. In addition, we are aware of other companies involved in early-stage nonclinical and clinical studies of similar somatostatin analogs. Most notably, Camurus AB is developing CAM2029, a subcutaneous octreotide depot for the potential treatment of neuroendocrine tumors and acromegaly. Camurus AB received FDA approval of its IND in June 2019 to initiate a Phase 3 acromegaly trial. MidaTech Pharma PLC also conducted its first in human study and also recently initiated a Phase 1 study of Q-Octreotide (MTD201), Midatech's injectable treatment for acromegaly built on its Q-Sphera sustained release platform technology. In 2019, Crinetics Pharmaceuticals, Inc. announced the initiation of two Phase 2 clinical trials to evaluate the safety and efficacy of CRN00808 in acromegaly patients. CRN00808 is a nonpeptide somatostatin agonist designed to be taken orally once per day. In May 2017, Dauntless Pharmaceuticals, Inc., a privately held biopharmaceutical company, announced positive results from its two-part, Phase 1 pharmacokinetic/pharmacodynamic study evaluating DP1038, a novel formulation of octreotide acetate for intranasal administration. In 2018, Ionis Pharmaceuticals initiated a Phase 2 trial of IONIS-GHR-$_{RX}$, its growth hormone receptor antagonist to control growth hormone production in acromegaly patients. In January 2020, Rani Therapeutics (RaniPill™ capsule containing octreotide) announced the completion of a Phase 1 study in 58 healthy volunteers, indicating that the RaniPill performed as designed. Per published reports, Rani Therapeutics plans to conduct a head-to-head study in acromegaly patients and demonstrate equivalence or non-inferiority to the injectable version of octreotide sc. We are also aware that Strongbridge Biopharm (valdoreotide or COR-005) may also be actively developing products for the maintenance treatment of acromegaly. If any or a combination of CAM2029, MTD201, CRN00808, DP1038, IONIS-GHR-$_{RX}$, RaniPill or the other products in development for acromegaly receive regulatory approval in a similar timeframe as our octreotide capsules, or demonstrate superior clinical results to octreotide capsules, we may encounter significant difficulties with our commercial launch of octreotide capsules.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. These companies also have long-established relationships within the medical and patient community, including patients, physicians, nurses and commercial third-party payors and government payors. Our ability to compete successfully will depend largely on our ability to:

- develop our product candidate and demonstrate that it is competitive with or superior to other products on the market;
- obtain required regulatory approvals;
- adequately communicate the benefits of octreotide capsules;
- attract and retain qualified personnel;
- obtain and maintain patent and/or other proprietary protection for octreotide capsules and any future product candidates we may develop; and
- in certain geographies, obtain collaboration arrangements to develop and commercialize octreotide capsules and any future product candidates we may develop.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render octreotide capsules or any future product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing octreotide capsules or any future product candidates we may develop.

Our competitors may also obtain FDA or other regulatory approval of their products more rapidly than we may obtain approval of ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and more advanced technologies become available. For example, a competitor could develop another oral formulation of either a somatostatin analog or non-somatostatin analog or other technology that could make administration of peptide-based therapies more convenient. If we are unable to compete effectively, our opportunity to generate revenue from the sale of octreotide capsules or any future product candidates we may develop, if approved, could be impaired.

The number of patients suffering from acromegaly is small and has not been established with precision. Our assumptions and estimates regarding prevalence may be wrong. If our octreotide capsules product candidate is approved for sale, and the actual number of patients in the applicable market is smaller than we estimate, our revenue could be adversely affected, possibly materially.

We estimate that there are an estimated 69,000 individuals with acromegaly in the developed world. The U.S. National Institutes of Health, or NIH, estimates that there are roughly 20,000 individuals with acromegaly in the United States, based on its published prevalence of an estimated 60 cases per million. In thirteen studies of acromegaly prevalence since 1980, an average of approximately 75 cases per million was determined, suggesting roughly 24,000 individuals with acromegaly in the United States. However, data presented at the Endocrine Society's Annual Meeting in 2015 suggest that pituitary tumors may be more prevalent than previously thought, and that the global prevalence of acromegaly may be higher, between 85 and 118 cases per million people. NIH also cites an annual incidence of three to four new cases per million each year. Data from a 2017 study by Lavrentaki et. al. suggest that the global prevalence of acromegaly may be between 28 and 137 cases per million people. Based upon our own market research, we believe that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analogs in the United States. However, there is no guarantee that these estimates are correct. The number of patients with acromegaly, in particular the number of patients for whom our octreotide capsules product is approved for use, could actually be significantly lower than these estimates.

We believe that the actual size of the total addressable acromegaly market in those markets in which our octreotide capsules product is approved, if at all, will be determined only after we have substantial history as a commercial company. If the total addressable market for our products is smaller than we expect, our revenue could be adversely affected, possibly materially.

****Octreotide capsules may not achieve or maintain an adequate level of acceptance by physicians, patients and third-party payors and government payors, and we may not generate sufficient revenue or be able to achieve or sustain profitability.***

The commercial success of octreotide capsules will depend in large part on the willingness of physicians to prescribe them to their patients. Octreotide capsules will compete against products that have achieved broad recognition and acceptance among medical professionals. In order to achieve and maintain an acceptable level of prescriptions for octreotide capsules, we must be able to meet the needs of both the medical community and patients with respect to cost, efficacy and other factors.

The degree of market acceptance of octreotide capsules will depend on a number of factors, including:

- the clinical safety, efficacy, tolerability and other factors regarding octreotide capsules observed in our completed ongoing and potential future clinical trials, including relative to injectable somatostatin analogs such as the relative topline data from our MPOWERED trial expected in the fourth quarter of 2020, and any other treatments available at the time;
- the relative convenience, number of capsules that need to be taken, requirement to fast before and after each dose of octreotide capsules, and other factors affecting the ease of administration;
- the prevalence and severity of any adverse effects;
- the incidence and prevalence of acromegaly patients in the United States that respond to and tolerate treatment with octreotide or lanreotide;
- the willingness of physicians to prescribe octreotide capsules and of the target patient population to try new therapies and adhere to them;
- the introduction of any new products that may in the future become available to treat indications for which octreotide capsules may be approved;
- changes in the clinical or economic profiles of alternative treatments;

- new procedures or methods of treatment that may reduce the incidences of any of the indications in which octreotide capsules may show utility;
- pricing and cost-effectiveness, particularly compared to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing, as well as disease education and awareness programs;
- the scope of the label approved by the FDA, which does not include efficacy data from our first Phase 3 clinical trial that demonstrated acromegaly symptom improvements in patients who completed the trial or comparable foreign regulatory authorities, and any future labels approved by the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in labeling approved by the FDA or comparable foreign regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement;
- competitor activities, including clinical trials in the United States for participants that are eligible for treatment with MYCAPSSA; and
- our ability to reliably manufacture and supply octreotide capsules.

In addition, even if we obtain the additional necessary regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize octreotide capsules successfully. For example, if the approval process for commercial supply of octreotide capsules in the United States takes too long, which is a greater likelihood as a result of our CBE-30 submission and planned submission of manufacturing supplement for the approval of the sources of commercial API required in order to have octreotide capsules available for our planned commercial launch, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any additional regulatory approval we ultimately obtain may be limited or be subject to restrictions or post-approval commitments that render octreotide capsules not commercially viable. For example, regulatory authorities may approve octreotide capsules for more limited indications than we request, may limit approved usage to narrower patient populations, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve octreotide capsules with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. The data from our completed first Phase 3 clinical trial that demonstrated acromegaly symptom improvements in patients who completed the trial, was not included in the FDA-approved label, and the CHIASMA OPTIMAL trial was not designed to, and did not, demonstrate validated symptom improvement data. While the MPOWERED trial employs a validated treatment satisfaction questionnaire for patient completion, the final symptom and treatment satisfaction data may be negative when comparing oral octreotide capsules to standard of care somatostatin analog injectables. Any of the foregoing could harm the commercial prospects for octreotide capsules.

Even if octreotide capsules are commercialized in the United States or are approved and commercialized in one or more additional geographies, they may not achieve and maintain an adequate level of acceptance by physicians, healthcare payors and patients, and we may not generate sufficient revenue or be able to achieve or sustain profitability. Any concerns about or negative perception of octreotide capsules or the clinical data of octreotide capsules within the patient or medical communities could significantly impact market adoption and commercial performance of octreotide capsules, even with the FDA approval to commercialize in the United States and if we are able obtain regulatory approval to commercialize in the European Union in the future. The perception of octreotide capsules within the patient and medical communities could be negatively impacted by clinical data from ongoing or future clinical studies, including comparative safety and efficacy data from the MPOWERED trial from which topline data is expected in the fourth quarter of 2020, as well as by real-world data on acromegaly treatments that we expect will be generated from our disease state registry for acromegaly. Our revenue and profitability may also be delayed during the potential period of time when commercial third-party payors and government payors are becoming familiar with octreotide capsules and patients are transitioning from injected alternatives to octreotide capsules. Our efforts to educate the medical community, patients and third-party payors on the benefits of octreotide capsules may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors, if the market for octreotide capsules decreases, we may not generate sufficient revenue.

**** We have only recently established sales, marketing and market access organizations and, as a company, have not commercialized any products. If we are unable to establish effective sales and marketing capabilities to commercialize octreotide capsules in the United States and access those capabilities in the European Union and other international markets if we secure necessary regulatory approvals, we may not succeed in commercializing octreotide capsules.***

We have only recently hired sales, marketing and market access personnel and expect to hire additional personnel. We have not engaged a partner to commercialize octreotide capsules in the United States, and, therefore, we currently intend to rely on our sales and marketing infrastructure to support commercial launch in the United States. Our sales, market access and marketing teams are limited in size and will have worked together for only a limited period prior to our anticipated commercial launch of octreotide capsules. We cannot guarantee that we will be successful in gaining coverage and or reimbursement with payers for MYCAPSSA or in driving utilization of octreotide capsules in the United States. We may not be able to establish an effective direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales, market access and marketing personnel. Factors that may inhibit our efforts to successfully commercialize octreotide capsules in the United States ourselves include:

- our inability to recruit and retain adequate numbers of effective sales, market access and marketing personnel;
- the inability of our relatively small planned sales force to obtain access to or inform adequate numbers of physicians, particularly the pituitary centers and the significantly larger number of community endocrinologists, about the potential benefits of octreotide capsules;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability to compete with larger, more established pharmaceutical sales and marketing organizations;
- the inability of market access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction;
- our inability to establish and maintain agreements and arrangements with third parties to effectively distribute MYCAPSSA to patients, including specialty pharmacies; and
- unforeseen costs, expenses and delays associated with creating a commercial organization.

Even though we obtained regulatory approval for commercializing octreotide capsules in the United States, we cannot guarantee whether we will be successful in marketing octreotide capsules in the United States. We also cannot guarantee whether we will be successful in marketing octreotide capsules in any other jurisdiction if we obtain the necessary regulatory approvals. If we are not successful in recruiting of sales and other commercial personnel on a timely basis or establishing an adequate sales, market access and marketing infrastructure and adequate distribution capabilities, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing octreotide capsules, if we obtain the necessary regulatory approvals, which could harm our business, operating results and financial condition.

If pursued by us, expansion of our business into the European Union and other international markets will require significant management attention and additional financial resources. We may explore commercializing octreotide capsules in the European Union and other international markets by entering into collaboration agreements with other biopharmaceutical companies, and we may not be successful in entering into these collaboration agreements. In the event that we do enter into such agreements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Additional factors and risks that may inhibit our efforts to commercialize octreotide capsules in foreign markets include:

- our inability to successfully commercialize octreotide capsules in the United States;
- our inability to directly control commercial activities because we are relying on third parties, should we enter into third-party collaborations;
- varying pricing in different foreign markets, including significantly lower prices for existing somatostatin analog injectables in European and other markets as well as the recent entry of generic somatostatin analog injectables into European markets, which could adversely affect our pricing in the European Union and other countries;

- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer collection times for accounts receivable;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives;
- foreign currency exchange rate fluctuations;
- our ability to obtain adequate reimbursement for octreotide capsules in foreign markets, either at all or at prices that exceed our costs; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of octreotide capsules could also be adversely affected by the imposition of governmental price controls, political and economic instability, trade restrictions and changes in tariffs.

We may not be able to establish a commercial operation in a cost-effective manner or realize a positive return on this investment, even with the assistance of one or more third-party collaborators, should we choose to enter into such an arrangement. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel.

If we or third-party collaborators are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into additional collaboration arrangements with third parties, we may not be able to successfully commercialize octreotide capsules or any future product candidates we may develop in foreign markets, which could impair our business, operating results and financial condition.

Even with the potential assistance of third-party collaborators, we may not be successful in establishing a commercial operation in foreign markets for numerous reasons, including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to establish a commercial operation in foreign markets will have a negative outcome on our ability to commercialize octreotide capsules and generate revenue.

Additionally, if approved for marketing in countries outside of the United States, we and/or our potential third-party collaborators may encounter unexpected or unforeseen delays in establishing our commercial operations that delay the commercial launch in these countries. These delays may increase the cost of and the resources required for successful commercialization of octreotide capsules both in the United States and internationally. We do not have any experience in a commercial launch in the United States, European Union or elsewhere.

We have only recently established a medical affairs organization and, as a company, have limited experience in operating a medical affairs organization. If we are unable to establish effective medical affairs capabilities in the United States and build or access them in the European Union and other international markets, our business may suffer.

We have only recently established our medical affairs organization. Medical affairs personnel are responsible for a number of key activities within biopharmaceutical companies, which include, but are not limited to, providing expert advice to other functions within the organization, advising on medical education activities, reviewing promotional and non-promotional communications, supporting medical and scientific publications, reviewing grants for third-party continuing medical education events, and providing an important scientific point of contact for physicians and scientists who seek to partner with us or better understand our science.

Failure to successfully execute these activities could harm our business in the following ways:

- our reputation among key physicians and scientists in acromegaly and other disease areas of interest to us may suffer;
- we may not be able to secure the advice and feedback of outside experts to help advance our knowledge and understanding of complex scientific and medical issues;
- our commercial and corporate functions may not receive adequate medical and scientific information in the creation of their external communications, which could lead to inaccurate information being disseminated about us, our product candidates, our disease areas of interest, or our other scientific endeavors;
- our promotional, non-promotional, grants, and medical events review processes may not provide an effective control to ensure compliance with applicable laws, regulations and standards; and
- we may not successfully interact with European or other ex-U.S. healthcare professionals and scientists who could help us execute plans for expansion into the European Union or other international markets.

We will need to grow the size of our organization in order to further establish our sales and marketing infrastructure, which is vital to our ability to successfully commercialize octreotide capsules, and we may experience difficulties in achieving and managing this growth.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize octreotide capsules in the United States. A commercial launch is a significant undertaking that requires substantial financial and managerial resources. As of July 31, 2020, we had 68 full-time employees. We have established sales and marketing infrastructure but as our development and commercialization plans and strategies evolve, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. The recruitment and hiring of these personnel will take time and could delay the commercialization of octreotide capsules. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize octreotide capsules and other product candidates we may develop and to compete effectively will depend, in part, on our ability to effectively manage any future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

****We will need to maintain an effective healthcare compliance program to support the sales and marketing of an approved drug in a manner that is compliant with applicable laws and regulations.***

Our marketing of pharmaceutical products is subject to extensive and complex laws and regulations. We have established and are administering a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems, and through the establishment and communication of a culture of compliance. We expect to continue to devote substantial resources to administer and grow this compliance program, but we may not be able to keep pace with the rapid growth and activity of the commercial organization. Among other laws, regulations and standards, we are subject to various U.S. federal and state laws, and comparable foreign laws pertaining to health care fraud and abuse, including anti-kickback and false claims statutes, laws prohibiting the promotion of drugs for unapproved or off-label uses, and laws requiring transparency regarding transfers of value to health care professionals and entities. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration to induce the referral of business, including the purchase or prescription of a particular drug; false claims laws prohibit anyone from presenting for payment to third-party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; and the Sunshine Act and other state and federal transparency laws require certain pharmaceutical manufacturers to track and report certain financial arrangements with physicians and teaching hospitals, including certain “transfers of value” provided to them, as well as certain ownership or investment interests held by physicians and their immediate family members. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Even if we obtain additional marketing approvals of octreotide capsules or any future product candidates we may develop, we will be subject to ongoing obligations and continued regulatory review, including with respect to the advertising and promotion of any product candidate that obtains approval.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by, among others, the FDA, the Department of Justice, or DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public, as well as by foreign regulatory authorities in the countries in which we commercialize octreotide capsules. The manufacture and marketing of octreotide capsules will be subject to ongoing regulation, including compliance with cGMPs, adverse event reporting requirements, guidance regarding the provision of reimbursement support and patient services, and general prohibitions against promoting products for unapproved or "off-label" uses. Violations of these ongoing regulations are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. Government investigation of these issues itself typically requires the expenditure of significant resources and can generate negative publicity, which could harm our business. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, engaging in impermissible promotion of our drug products for "off-label" uses can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to significant administrative civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. In recent years, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to substantial civil and criminal settlements based on certain sales practices promoting "off-label" drug uses. This increasing focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs, among other penalties. If we do not lawfully promote our approved products, we may become subject to such litigation and/or investigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable. In addition, any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. For example, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs, are strictly regulated in the European Union under Directive 2001/83EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the European Union.

**** The manufacture and packaging of pharmaceutical products such as octreotide capsules are subject to FDA requirements and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be harmed.***

The manufacture and packaging of pharmaceutical products, such as octreotide capsules are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMP regulations who are both capable of manufacturing octreotide capsules and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture the API, for octreotide capsules. The third-party contract manufacturers that we utilize or plan to utilize for commercial supply have been subject to regulatory inspections from time to time that resulted in inspectional observations. For example, in the CRL, the FDA advised that, during a site inspection, certain deficiencies were conveyed to the representative of one of our suppliers. In addition, we did not reference in the NDA that the FDA recently approved our planned primary commercial API manufacturer due to unresolved observations from a recent regulatory inspection at the time of NDA resubmission. We expect that our suppliers will be subject to additional regulatory inspections in the future, including in connection with the FDA's review

of our CBE-30 supplement and our planned additional manufacturing supplement. Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer such as those we proposed in our CBE-30 supplement and we expect to propose by submitting our planned additional manufacturing supplement to the FDA, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMP requirements. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the planned commercial launch of our product.

Furthermore, in order to obtain additional approvals of our current or future product candidates, including octreotide capsules, by the FDA and foreign regulatory agencies, we will be required to consistently produce the API and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. In order to secure sources of commercial quantities of API to support our planned commercial launch of octreotide capsules, on June 29, 2020, we submitted to the FDA a CBE-30 supplement and plan to submit a second manufacturing supplement to the NDA, which we expect will be a prior approval manufacturing supplement, for sources of commercial API. In April 2020, the FDA requested that we include certain stability data in our planned second manufacturing supplement, which we expect will result in a planned submission of this supplement in early 2021. The review of any manufacturing supplement to the NDA will require FDA review and approval of the manufacturing process, facility, equipment and procedures in place at each manufacturing site, including batch-to-batch comparability and API and drug product stability data, in accordance with the FDA's cGMP requirements and may require regulatory inspections of each manufacturing site, which could prevent or delay approval of any such manufacturing supplement. If we are unable to obtain approval of one of the two manufacturing supplements, we may be unable to secure API and the finished oral octreotide product in commercial quantities and our commercialization efforts may be harmed. The timing of the FDA's review process related to our CBE-30 supplement or planned manufacturing supplement and the outcome of such review are inherently uncertain, and we can provide no assurances that the CBE-30 supplement or planned manufacturing supplement will be approved in a timely manner or at all.

In addition, we expect our primary supplier for commercial API will require additional qualified capacity to meet future demand and each of our planned API suppliers may use a different method to manufacture API, which has the potential to increase the risk to us that our manufacturers will fail to meet our commercial demand for API or applicable regulatory requirements. If we obtain the necessary regulatory approvals to commercialize octreotide capsules, we will also need to complete required testing on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, commercial supply and launch may be delayed.

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacturing, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could harm our business.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of octreotide capsules and any future product candidates we may develop may be delayed, our business will be harmed and we may not have sufficient resources to continue as a standalone company.

We estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory, product development and commercialization objectives. These milestones may include our expectations regarding the commencement or completion of clinical trials, the submission of regulatory filings, or initiation of commercialization. From time to time, we may publicly announce the expected timing of some of these milestones, such as the initiation or completion of an ongoing clinical trial, submission of a marketing application for approval, receipt of marketing approval, or a commercial launch of a product. The achievement of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our strategic decisions on the design and conduct of our clinical trials;
- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;

- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of octreotide capsules and any future product candidates we may develop;
- the efforts of our collaborators and the success of our own efforts with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones, including regulatory approvals, in the timeframes we announce and expect, the commercialization of octreotide capsules and any future product candidates we may develop may be prevented or delayed and our business and results of operations may be harmed.

Octreotide capsules and other products we may develop may not be commercially viable if we fail to obtain coverage and an adequate level of reimbursement for these products from governmental payors, including Medicare and Medicaid programs, private insurers, and other third-party payors. The market for octreotide capsules and other products we may develop may also be limited by the indications for which their use may be reimbursed.

The availability of coverage and adequate levels of reimbursement by governmental and other third-party payors will affect the market for octreotide capsules and subsequent products that we may develop, if any. These third-party payors continually attempt to contain or reduce the costs of health care, such as by challenging the prices charged for medical products and services and by applying value assessments to clinical outcomes using different safety and efficacy standards than used for marketing approval by the FDA and the EMA.

In the United States, we will seek to obtain reimbursement for octreotide capsules from third-party payors. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were enacted in 2010 with the passage of the Affordable Care Act, or the ACA. These reforms could significantly reduce payments from Medicare and Medicaid in the future. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from governmental payors, private insurers and other third-party payors for octreotide capsules and any other potential products we may pursue. Some of these changes and proposed changes could result in reduced reimbursement rates for octreotide capsules and any other potential products we may pursue, which would adversely affect our business strategy, operations and financial results.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a governmental or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

We have determined a wholesale acquisition cost, or WAC, for octreotide capsules that increases linearly in accordance with the approved dosing levels of MYCAPSSA – 40mg, 60mg, or 80mg per day. Octreotide and lanreotide product pricing is also dose dependent, and have lower WAC prices at certain dose levels. We expect that private insurers will consider the efficacy, cost effectiveness and safety of octreotide capsules as well as the relative pricing of competing injectable somatostatin analogs in determining whether to provide reimbursement for octreotide capsules and at what level. Obtaining these additional approvals for reimbursement can be a time-consuming and expensive process. Even though we received regulatory approval to market octreotide capsules in the United States, our business would be harmed if we do not receive approval of reimbursement of octreotide capsules from third-party payors on a timely or satisfactory basis. Medicare does not cover particular drugs if it determines that they are not “reasonable and necessary” for its beneficiaries. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be harmed if Medicare, local Medicare carriers or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of octreotide capsules.

Our business could also be harmed if governments, private insurers, Medicare, Medicaid or other reimbursing bodies or payors limit the indications for which octreotide capsules will be reimbursed to a smaller set than we believe it is safe and effective in treating, or establish a limitation on the frequency with which octreotide capsules may be administered

that is less often than we believe would be safe and effective, or establish a limitation on dose that is lower than we believe would be safe and effective. In addition, even if we receive additional regulatory approvals, regulatory authorities may introduce significant restrictions to the label for octreotide capsules in an effort to address certain concerns about the product or product candidate, including concerns raised during any review of data from the MPOWERED trial. We expect to report top-line data from the MPOWERED clinical trial in the fourth quarter of 2020, which will provide biochemical control data (GH and IGF-1) of octreotide capsules as compared to the standard of care injectable somatostatin analogs, octreotide LAR and lanreotide depot, as well as patient treatment satisfaction and symptom control data. If reported MPOWERED data is unfavorable, the reimbursement rates and market potential for octreotide capsules in the United States could be severely limited. Any such restrictions or potential reservations about efficacy expressed by regulatory authorities or within the medical community could significantly impact reimbursement, market adoption and commercial performance of octreotide capsules.

We expect to experience pricing pressures in connection with the sale of octreotide capsules and any future product candidates we may develop, if required regulatory approvals are obtained, due to healthcare reforms, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations, additional legislative proposals, competitive pricing pressures, including potential generic entrants, and the economic health of companies. If coverage and reimbursement for our products are unavailable, or are limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

In Europe and many other foreign countries, the pricing of prescription pharmaceuticals is subject to governmental control, and each country has a different reviewing body that evaluates reimbursement dossiers submitted by holders of marketing authorizations for new drugs. That governing body then makes recommendations as to whether or not the drug should be reimbursed and will often consider the reimbursement levels of competing marketed standards of care. For example, injectable somatostatin analogs currently marketed in the European Union are reimbursed at levels that are far less than in the United States on a per patient, per year basis. The pricing of octreotide capsules in the European Union, if approved, will likely be determined by government payors following an assessment of the relative efficacy, safety and benefits of octreotide capsules versus standard of care somatostatin analog injections. We believe the MPOWERED trial will provide the information required to make these assessments, and if octreotide capsules are deemed inferior to standard of care injectable somatostatin analogs, octreotide capsules may lose its orphan designation in the European Union and receive pricing determination decisions at levels that are less than standard of care injectables, which would severely impact our ability to profitably market octreotide capsules in the European Union. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate, such as octreotide capsules, to other available therapies. Future U.S. pharmaceutical pricing regulations may require that the U.S. price for octreotide capsules be referenced to the lower or lowest price levels of the product, or competing somatostatin analogs, as set in other ex-U.S. countries, which reference pricing impact could significantly harm our business.

The longer-term growth of our business depends on our efforts to expand the approved uses of octreotide capsules beyond acromegaly and leverage our TPE platform to expand our portfolio of product candidates, which may require substantial financial resources and may ultimately be unsuccessful.

The longer-term growth of our business depends upon our ability to expand the approved uses of octreotide capsules beyond acromegaly and utilize our proprietary Transient Permeability Enhancer, or TPE, technology platform to potentially develop and commercialize other oral forms of therapies that are currently only available in injectable or other non-absorbable forms. In addition to the development and commercialization of octreotide capsules as a treatment for acromegaly, we may pursue development of octreotide capsules for other indications or develop other product candidates alone or in collaboration with other parties. Because we eliminated substantially all of our research and discovery functions during the August 2016 reduction in workforce, we now have only limited internal capacity to develop any new product candidates. We also may never be able to identify other peptide drugs or poorly absorbed small-molecule drugs that can successfully be developed into product candidates utilizing our TPE platform, let alone receive regulatory approval of such product candidates, and we may never be able to engage in licensing transactions that enable a third party to utilize TPE in the development of future product candidates.

Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any product candidates, and we are not currently materially investing in such research programs. As a result, we may not be able to successfully identify any future product candidates or new indications for octreotide capsules.

There are a number of FDA, EMA and other health authority, as applicable, requirements that we must satisfy before we can commence a clinical trial. If we are able to identify additional potential product candidates, satisfaction of these regulatory requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on development of other product candidates may impair our ability to continue development and commercialization of octreotide capsules for the treatment of acromegaly and other indications, if pursued, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of octreotide capsules in other indications besides acromegaly or other product candidates, these product candidates may never demonstrate sufficient safety and efficacy to be approved by the FDA or other regulatory authorities.

Our ability to develop a viable pipeline of potential future products may require us to enter into acquisition, license or similar agreements with third parties, and we may not be successful in negotiating the necessary agreements, or in achieving economic terms that will be sufficiently favorable to justify development of one or more such future products.

As a result of the elimination of substantially all of our research functions, we are currently unable to develop future potential products through internal research programs. Therefore, we may consider expanding the scope of future potential product candidates by acquiring or licensing product candidates, discovery programs or other technologies from third parties or licensing our TPE technology to third parties.

We may, however, be unable to license or acquire suitable product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is a competitive area. For example, several more established companies are also pursuing strategies to license or acquire products in the somatostatin analog or endocrinology field. These established companies may have a competitive advantage over us due to their size, cash resources and greater research, clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

- we may be unable to license or acquire the relevant product candidate or technology on terms that would allow us to make an appropriate return, or the financial terms required by the owners of those product candidates or technologies may be unfavorable enough to preclude successful development and commercialization for such products;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us;
- we do not currently have dedicated research or business development personnel on staff;
- we may be unable to identify suitable products or product candidates within our areas of expertise; or
- if we are unable to successfully commercialize octreotide capsules in the United States in a timely manner or at all third-party confidence in our TPE platform could be reduced and potentially make us a less attractive partner.

In addition, even if we are able to successfully license or acquire suitable technology from third parties, there can be no assurance that we will be able to successfully develop product candidates from such technology or receive necessary approvals to commercialize any such product candidates.

We only have limited human and financial resources to develop suitable potential product candidates through internal research programs, we may not have the resources to obtain rights to technologies or product candidates from third parties, and we may not be able to license our TPE technology to third parties for development of future product candidates, thereby limiting our ability to develop a diverse product portfolio. If we are unable to develop such a portfolio, our business may suffer.

We may be unable to obtain and maintain orphan drug designation or exclusivity for oral octreotide or future product candidates we may develop. If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Our octreotide capsules product candidate has been granted orphan designation in the United States and the European Union for the oral treatment of acromegaly. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, as amended, the FDA may designate a product candidate as an orphan drug if it is intended to treat a

rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals diagnosed annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Commission, after reviewing the opinion of the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the product candidate. Even if we request orphan drug designation for any future product candidates we may develop, there can be no assurances that the FDA or the European Commission will grant any of these product candidates such designation. Additionally, the designation by the FDA or the European Commission of any potential product candidates as an orphan drug does not guarantee that the FDA or the EMA will accelerate regulatory review of or ultimately approve that product candidate.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval of the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and 10 years in the European Union. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug designation for octreotide capsules in the United States[, the orphan drug exclusivity determination is pending the FDA's decision] as a treatment for acromegaly] and orphan drug designation for octreotide capsules in the European Union as a potential treatment for acromegaly and may obtain orphan drug designation for octreotide capsules in other indications or for future product candidates we may develop, we may not obtain orphan drug exclusivity and any such exclusivity that we do obtain may not effectively protect the product candidate from competition because different drugs can be approved for the same condition and the same drugs can be approved for different indications and might then be used off-label in our approved indication, if obtained. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that such later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, if a potential future product candidate of ours receives an orphan drug designation and is approved for a particular indication or use within the rare disease or condition, the FDA may later approve the same drug for additional indications or uses within that rare disease or condition that are not protected by our exclusive approval. As a result, if our product is approved and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us. Similarly, the European Commission may grant a marketing authorization for a similar medicinal product in the same therapeutic indication if the second applicant can establish that although their product is similar to the orphan medicinal product already authorized, the second product is safer, more effective or otherwise clinically superior.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of octreotide capsules and any future product candidates we may develop for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our operations and expose us to areas of risk including the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of certain individually identifiable health information;
- the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws which govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative or regulatory reform of the health care system in the United States and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the ACA was signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans;
- the definition of "average manufacturer price" was revised for reporting purposes, which could increase the amount of Medicaid drug rebates by state;
- the 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities;
- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "donut hole"; and
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs. If octreotide capsules or any of our future potential product candidates are approved, we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, and therefore would not expect this annual assessment to have a material impact on our financial condition.

Despite initiatives to invalidate the ACA, the U.S. Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate, and a key provision of the ACA, which provides federal premium tax credits to individuals purchasing coverage through health insurance exchanges.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. As a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, which will remain in effect until 2029 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products. Other legislative and regulatory initiatives have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. For example, the Drug Supply Chain Security Act of 2013 imposes new obligations on manufacturers of certain pharmaceutical products related to product tracking and tracing. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance documents or interpretations

will be changed, or what the impact of such changes on the marketing approvals of octreotide capsules, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Further, in some foreign jurisdictions, including the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of octreotide capsules and any future product candidate we may develop to other available therapies. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from octreotide capsules and any other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Product liability lawsuits could cause us to incur substantial liabilities and limit potential commercialization of oral octreotide or other product candidates we may develop, and we may not be able to maintain our current product liability coverage, and, even if we do, our coverage may not be adequate to cover any or all liabilities that we may incur, which could decrease our cash and harm our business.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. For example, we may be sued if any drug we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy;
- potential disputes, including litigation, with our insurance provider regarding coverage and
- the inability or significant limitations on the ability to commercialize any drugs that we may develop.

We currently have $10.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover any or all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability insurance coverage to include the sale of commercial products as we prepare to commercialize octreotide capsules and if we obtain additional marketing approvals of octreotide capsules and any future product candidates we may develop, but we may be unable to obtain commercially reasonable product liability insurance. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and harm our business. In addition, we may not be able to maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

Risks Related to Our Reliance on Third Parties

**** We are, and expect to be for the foreseeable future, dependent on a limited number of third parties to manufacture octreotide capsules.***

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the API in octreotide capsules for use in our clinical trials or for commercial product, if regulatory approvals are obtained. We have qualified Novetide Ltd., a subsidiary of Teva Pharmaceuticals Industries Ltd., in Israel and an affiliate of Teva API, Inc., and Bachem Americas Inc. in the United States as our suppliers of the generic API, octreotide acetate. The octreotide API is lyophilized, formulated with our TPE technology by Lyophilization Services of New England Inc., or LSNE, in Bedford, NH, and enteric-coated and blister packed by Capsugel, a division of Lonza, in Scotland. Almac Pharma Services Limited in Northern Ireland provides finished packaging and release services.

The facilities used by our contract manufacturers to manufacture octreotide capsules are evaluated by the FDA and other regulatory bodies. We are completely dependent on our contract manufacturing partners for compliance with cGMPs for manufacture of both API and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to octreotide capsules. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval of our product candidate being manufactured at their manufacturing facilities. If the FDA or a comparable foreign regulatory authority finds deficiencies at these facilities, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval of or market octreotide capsules. The third-party contract manufacturers that we utilize or plan to utilize for commercial supply have been subject to regulatory inspections from time to time that resulted in inspectional observations. For example, we did not reference in our approved NDA our planned primary commercial API manufacturer due to unresolved observations from a recent regulatory inspection at the time of NDA resubmission. We expect that our suppliers will be subject to additional regulatory inspections in the future, including in connection with the review of our CBE-30 and other planned manufacturing supplement. There can be no assurances that our suppliers will pass all necessary inspections, the failure of which could result in delays to our ability to receive regulatory approval for octreotide capsules.

Our NDA that was approved by the FDA in June 2020 references one small-scale API manufacturer that was included in our original NDA and is owned by our planned secondary commercial API manufacturer. However, we do not expect to procure commercial API from this small-scale manufacturing site. Accordingly, in order to commercially launch octreotide capsules, on June 29, 2020, we submitted to the FDA a manufacturing supplement to the NDA as a CBE-30 supplement to provide for the approval of our primary API manufacturer and one of its large-scale manufacturing sites. In addition, we also plan to file a second manufacturing supplement to the NDA, which we expect will be a prior approval manufacturing supplement, to provide for a large-scale manufacturing site affiliated with the small-scale manufacturing site referenced in the NDA. In April 2020, the FDA requested that we include certain stability data in this planned prior approval manufacturing supplement, which we expect will result in a planned submission of this supplement in early 2021. The review of any manufacturing supplement to the NDA will require FDA review and approval of the manufacturing process, facility, equipment and procedures in place at each manufacturing site, including batch-to-batch comparability and API and drug product stability data, in accordance with the FDA's cGMP requirements and may require regulatory inspections of each manufacturing site, which could prevent or delay approval of any such manufacturing supplement and prevent or delay our planned commercial launch.

In addition, our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and requirements. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market octreotide capsules, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could harm our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these requirements could impair our ability to develop, obtain regulatory approval of or market octreotide capsules.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to effectively terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them, and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished octreotide capsules product or should cease doing business with us, we could experience significant interruptions in the supply of octreotide capsules or may not be able to create a supply of octreotide capsules at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of octreotide capsules might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or their inability to increase and maintain their capacity to meet our commercial demand, could impair our ability to supply octreotide capsules at required levels. Because of the significant regulatory requirements that are necessary to qualify a new API or finished product manufacturer or to qualify a new or existing site for a current manufacturer, which we are pursuing with our submission of a CBE-30 supplement and planned submission of a second manufacturing supplement for our planned sources of commercial API, we could experience significant interruptions in the supply of octreotide capsules if such regulatory qualifications are withheld or delayed, especially if we decided to transfer the manufacture of API or finished octreotide capsules to one or more alternative manufacturers in an effort to deal with any manufacturing, qualification or other difficulties.

Any manufacturing problem or the loss of a contract manufacturer or our failure to obtain FDA approval of our CBE-30 supplement or planned second manufacturing supplement could be disruptive to our operations and, if our products receive marketing approval, result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture octreotide capsules. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacturers caused by problems at suppliers could delay shipment of octreotide capsules and increase our cost of goods sold and result in lost sales.

We cannot guarantee that our current manufacturing and supply partners or any alternative service providers will be able to reduce the costs of commercial-scale manufacturing of octreotide capsules over time, particularly following the suspension of our commercial commitments to certain of our manufacturers following the receipt of the CRL. If the manufacturing costs of octreotide capsules remain at current levels or increase, these costs may significantly impact our future operating results. In order to reduce costs and improve efficiencies, we plan to develop and implement process improvements and produce octreotide capsules at a larger scale. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to produce sufficient quantities of octreotide capsules or reduce our costs over time, which could be detrimental to the profitability of octreotide capsules in any market, and particularly the EU market where substantially lower prices are expected if we are able to secure marketing approvals for octreotide capsules there.

We have previously established commercial manufacturing agreements with Teva API, Inc. for the API in octreotide capsules and with LSNE for certain testing and lyophilization services. Following our receipt of the CRL in 2016, we indefinitely suspended our commercial production commitments and only recently reinitiated commercial production planning with these suppliers. We have also more recently entered into commercial supply agreements with Lonza, Bachem and Almac. In the future we may not be able to reach or maintain agreements containing terms that are acceptable to us with our commercial manufacturers.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed requirements, we cannot completely eliminate the risk of contamination or injury resulting from such materials. As a result of any such contamination or injury we may incur liability or local, city, state or federal authorities may curtail the use of these materials, interrupting our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts, which could harm our business, prospects, financial condition or results of operations.

An important part of our strategy may be to enter into licensing or collaboration agreements with respect to octreotide capsules and future product candidates, if any, in certain territories. We may not be able to identify suitable collaborators and, even if we do, our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Our strategy for commercializing octreotide capsules and any future product candidates we may develop may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we may seek to partner. Despite our efforts, we may be unable to secure collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs.

Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In the event we grant exclusive rights to such partners, we could be precluded from potential commercialization of our product candidate within the territories in which we have a partner. In addition, any termination of our collaboration agreements will terminate any funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may harm our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

We rely, and will rely in the future, on third parties to conduct our clinical trials. If these third parties do not appropriately carry out their contractual duties, fail to conduct high-quality studies or meet expected deadlines, regulatory approval and commercialization of octreotide capsules or any future candidates we may develop could be delayed or not obtained at all.

We do not have the ability to conduct our clinical trials independently. We will continue to rely on third parties, including clinical investigators, third-party CROs and consultants, to monitor, manage data for, and execute our ongoing clinical programs for octreotide capsules, and we control only some aspects of their activities. Because we rely on third parties, our internal capacity to perform these functions is limited. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. Nevertheless, we are responsible for ensuring that each of our clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific requirements and standards, including, for example, Good Laboratory Practices and Good Clinical Practices, or GCPs. Our reliance on third parties does not relieve us of our regulatory responsibilities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the relevant regulatory authorities may require us to perform additional clinical trials in support of our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. Failure to comply with these regulations may require us to repeat nonclinical studies and clinical trials, which would delay the regulatory approval process.

The third parties conducting our clinical trials are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical programs. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain additional regulatory approvals of or successfully commercialize octreotide capsules and any future product candidates we may develop. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed.

Risks Related to Our Financial Position and Capital Resources

We have incurred significant losses since our inception and anticipate that we will incur continued losses for the next several years and thus may never achieve or maintain profitability.

We have funded our operations to date primarily through proceeds from sales of our common stock, redeemable convertible preferred stock and, to a lesser extent, the issuance of convertible notes. As of June 30, 2020, our cash, cash equivalents and marketable securities were $67.1 million. Since inception, we have incurred significant operating losses. Our net loss was $36.5 million for the six months ended June 30, 2020 and $36.3 million for the year ended December 31, 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $309.4 million.

We have one product approved for commercialization and have never generated any product revenue. We expect to incur operating losses for at least the next several years. Past operating losses, combined with expected future operating losses, have had and will continue to have an adverse effect on our cash resources, stockholders' equity and working capital. We expect to incur significant additional costs conducting and completing our MPOWERED clinical trial, to fund our operations in support of this clinical trial, to pursue regulatory approvals, to prepare for commercialization and to manufacture and commercialize octreotide capsules. In addition, we will continue to incur additional costs associated with operating as a public company. As a result of these and other factors, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses, when we will become profitable, if at all, or whether we will have the funds necessary to continue as a standalone business in the long term.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our stock and impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals, diversify our product pipeline or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

**** Our Revenue Interest Financing Agreement with Healthcare Royalty Partners IV, L.P. could restrict our ability to commercialize MYCAPSSA, limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.***

On April 7, 2020, we entered into the Revenue Interest Financing Agreement with Healthcare Royalty Partners IV, L.P., or HCR. Under the terms of the Revenue Interest Financing Agreement, we received $25.0 million in April 2020, received an additional $25.0 million in July 2020, and are entitled to receive an aggregate of up to an additional $25.0 million, subject to the satisfaction of certain conditions, in exchange for tiered quarterly royalty payments in the low double digits on worldwide net revenues of MYCAPSSA and any other future products, subject to step-downs upon the achievement of certain annual revenues. The Revenue Interest Financing Agreement expires upon the first to occur of April 7, 2030, or the Maturity Date, or when HCR has received aggregate payments equal to 195% of the total amount actually funded by HCR, or the Hard Cap. If HCR has not received the Hard Cap by the Maturity Date and no event of default has occurred or is ongoing, among other things, we must pay HCR a specified amount based on the total amount funded by HCR as of such date. Upon the occurrence of an event of default, including the withdrawal, suspension or other termination of the FDA approval of MYCAPSSA as a treatment for acromegaly that continues for sixty days that prevents us from marketing MYCAPSSA, HCR may accelerate payments due under the agreement up to the Hard Cap. Upon the occurrence of certain material adverse events or the material breach of certain representations and warranties, which will not be considered events of default, HCR may elect to terminate the agreement and require us to make payments to HCR equal to the funded portion of the investment under the agreement, minus payments received by HCR, plus a specified annual rate of return.

We must make gross up payments to HCR on September 30, 2023 and September 30, 2024, to the extent HCR has not received royalty payments totaling 60.0% and 100.0%, respectively, of the amount it has invested as of such dates. If a change of control occurs, we must immediately repay HCR the total amount actually funded plus a change of control premium, the amount of which is variable up to 95% based on timing and circumstances of such change of control and

the amount funded and conditionally eligible to be funded by HCR as of the date of the change of control. Under the terms of the Revenue Interest Financing Agreement, we have certain obligations, including the obligation to use commercially reasonable and diligent efforts to commercialize MYCAPSSA ourselves in the United States. If we are held to not have met these obligations, HCR would have the right to terminate the Revenue Interest Financing Agreement and demand payment equal to the funded portion of its investment amount, plus a specific annual rate of return per annum on HCR's investment amount, less amounts paid by us. The Revenue Interest Financing Agreement also requires us to obtain the consent of HCR prior to incurring additional indebtedness, other than specified permitted indebtedness. Further, the Revenue Interest Financing Agreement requires us to maintain a minimum of $20.0 million in securitized cash and investment accounts during any quarter that the trailing four quarters of net revenue of MYCAPSSA is below a certain threshold.

Our indebtedness under the Revenue Interest Financing Agreement could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing or enter into MYCAPSSA partnership agreements;
- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and
- if we fail to comply with the terms of the Revenue Interest Financing Agreement, resulting in an event of default that is not cured or waived, HCR could seek to enforce its security interest in our cash and cash equivalents and all assets relating to MYCAPSSA that secures such indebtedness.

To the extent we incur additional debt (including without limitation additional amounts under the Revenue Interest Financing Agreement), the risks described above could increase.

We have not generated revenue from any commercial products and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. We only recently obtained FDA approval of octreotide capsules for the treatment of acromegaly and are still in the process of executing our commercial launch plan as we work towards commercial product availability. We have no history of commercializing products and, to date, have not generated revenue from the sale of any commercial product. Unless and until the necessary regulatory approvals for our CBE-30 manufacturing supplement and planned second manufacturing supplement for octreotide capsules are obtained from the FDA or necessary regulatory approvals outside the U.S. or for any future product candidates we may develop are obtained, we may not be able to generate sufficient revenue to attain profitability. In addition, our ability to generate profits after the FDA approval of octreotide capsules for the treatment of acromegaly or other regulatory approvals of octreotide capsules or any product candidates we may develop is subject to our ability to obtain and maintain regulatory approval of our planned commercial contract manufacturers and manufacturing sites, to contract for the manufacture of commercial quantities of our product candidates at acceptable cost levels and establish sales, market access and marketing capabilities or identify and enter into one or more strategic collaborations to effectively market and sell any approved product candidate.

Even if we obtain additional regulatory approvals for octreotide capsules or any future product candidates and launch the commercial sale, any approved product may not gain market acceptance or achieve commercial success. In addition, we anticipate continuing to incur significant costs associated with commercializing octreotide capsules and would anticipate incurring significant costs associated with commercializing any other approved product. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient levels of product revenues, we will not become profitable and may be unable to continue operations without continued funding.

We have a limited operating history and no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Although we commenced operations in 2001, our operations to date have been largely focused on developing octreotide capsules, including undertaking nonclinical studies and conducting clinical trials, and preparing for the commercial launch of octreotide capsules in the United States. Our oral octreotide capsules product is our only product for which we have conducted clinical trials and obtained a regulatory approval. We have completed only two Phase 3 clinical trials to date with oral octreotide, and we are currently conducting one additional Phase 3 clinical trial of octreotide capsules in acromegaly. In June 2020, we obtained FDA approval of octreotide capsules for the treatment of acromegaly. We have a limited history of obtaining regulatory approvals and have not yet demonstrated our ability to successfully obtain regulatory approvals outside the United States, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf, or conduct sales, market access and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We are transitioning from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition in the United States, which is planned in 2020, or in the European Union or elsewhere.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, stockholders should not rely upon the results of any particular quarterly or annual periods as indications of future operating performance.

**** We will need additional capital to support our operations, which may be difficult to obtain and restrict our operations and would result in additional dilution to our stockholders.***

Our business will require additional capital that we have not yet secured. In the short term, we expect our manufacturing costs and selling, general and administrative expenses to increase as we to continue to establish the infrastructure and manufacture the commercial supply for a planned commercial launch of octreotide capsules in the United States expected to commence in the fourth quarter of 2020. We will also continue to incur research and development expenses as we , conduct and complete our MPOWERED clinical trial, for which we expect top-line data in the fourth quarter of 2020, undertake activities to support the planned submission of an MAA to the EMA for regulatory approval of oral octreotide in the European Union for acromegaly, assuming positive data from the MPOWERED Phase 3 trial, and pursue early clinical development of one or more potential pipeline candidates using our TPE platform technology. Because the outcome of any clinical trial, regulatory approval process and commercialization efforts is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of oral octreotide capsules or any future product candidates we may develop. We may be unable to raise capital when needed or on attractive terms, or to enter into collaboration agreements, which could force us to delay, limit, reduce or terminate our product development efforts or preparations for our anticipated commercial launch of oral octreotide capsules.

The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include but are not limited to:

- our efforts to obtain FDA approval of our manufacturing supplements for our commercial API manufacturing sources, and to conduct and complete our MPOWERED clinical trial;
- the amount of our future operating losses;
- the costs associated with establishing and maintaining the infrastructure to support our planned commercial launch of octreotide capsules;
- the timing of approvals, if any, of octreotide capsules in additional jurisdictions;
- the need and cost of conducting one or more additional clinical trials for octreotide capsules and any future product candidates;
- the amount of our research and development, marketing, selling and general and administrative expenses;
- the extent to which we enter into, maintain, and derive revenues from licensing agreements, including potential agreements to out-license octreotide capsules, research and other collaborations, joint ventures and other business arrangements;

- our success in integrating product candidates, technologies or companies that we may acquire; and
- regulatory changes and technological developments in our markets.

General market conditions or the market price of our common stock may not support capital-raising transactions, such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on The NASDAQ Global Select Market or upon obtaining stockholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on The NASDAQ Global Select Market or that we will be able to obtain stockholder approval if it is necessary. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease development or commercialization of octreotide capsules, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, including pursuant to our ATM Agreement, convertible debt financing, license and collaboration agreements with potential partners. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. The terms of any debt facility, if available, may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to develop and commercialize octreotide capsules or any future product candidates or operate our business. For example, during the term of the Revenue Interest Financing Agreement with HCR, we must obtain the consent of HCR prior to incurring additional indebtedness, other than specified permitted indebtedness, and we must maintain a minimum of $20.0 million in securitized cash and investment accounts during any quarter that the trailing four quarters of net revenue of MYCAPSSA is below a certain threshold. Any of these actions could raise substantial doubt about our ability to continue as a standalone business, materially impair our ability to remain in business and have a material adverse effect on our business, financial condition and results of operations.

**** Unstable market and economic conditions, including as a result of the novel coronavirus COVID-19 pandemic, may have serious adverse consequences on our business, financial condition and stock price.***

As widely reported, global credit and financial markets have experienced recent volatility and disruptions, including diminished liquidity and credit availability, predicted declines in economic growth, and uncertainty about economic stability, including as a result of the economic impact to the novel coronavirus COVID-19 pandemic. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. For example, given the pandemic, if a substantial number of acromegaly patients become unemployed or lose health insurance coverage, they may not be able to pay all or a portion of their prescription cost of octreotide capsules. If the current equity and credit markets deteriorate, it may make any necessary convertible debt or equity financing more difficult, more costly and more dilutive for us to achieve. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development and commercialization plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may be negatively impacted or not survive an economic downturn, which could directly affect our ability to attain our operating goals.

**** Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.***

We may seek additional capital through a combination of private and public equity offerings, convertible debt financings and collaboration, strategic and licensing transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. For example, as described above, during the term of the Revenue Interest Financing Agreement with HCR, we are restricted from incurring certain additional indebtedness without HCR’s consent and must satisfy a minimum liquidity covenant except during periods when we have met certain MYCAPSSA revenue thresholds. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to pay royalties to HCR on annual revenues and/or payments received by us, and may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us.

Risks Related to Our Business and Industry

**** Pandemics such as the coronavirus could have an adverse impact on our business and our financial condition.***

In December 2019, a novel strain of coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. These could include disruption to our regulatory approval timelines due to diversion of government resources, delays in planned commercialization efforts due to manufacturing delays, slowed hiring of commercial personnel, limitations on face to face interactions with potential customers or other issues, restrictions on our ability to travel, attend in-person meetings, participate in industry conferences, pursue partnerships and other business transactions, disruption of our clinical trials, as well as impacts from the temporary closure of the facilities of suppliers and clinical trial sites or an overburdened healthcare system. Any continued and future disruption of regulators, physicians, suppliers, shippers, third-party warehouses, clinical trial sites or access to physicians or patients could impact our regulatory approval timing, commercialization efforts as well as our ability to access capital through the financial markets. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

We depend on the knowledge and skill of our senior management and other key employees, and if we are unable to retain or if we fail to recruit additional highly skilled personnel, our business will be harmed.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial and development personnel. As of July 31, 2020, we have a total of 68 full-time employees. In order to induce valuable employees to remain with us, we have provided employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and, together with our other compensation programs and benefits, may at any time be insufficient to counteract more lucrative offers from other companies.

We are highly dependent upon the principal members of our management team. These executives have significant commercial, research and development, regulatory, industry, operational, and/or corporate finance experience. The loss of any executive, other principal member of our management team, key employee or member of our board of directors could impair our ability to develop and commercialize octreotide capsules and identify, develop and market new products and conduct successful operations.

In addition, with the FDA approval of octreotide capsules, we will likely need to hire a significant number of qualified technical, commercial, medical and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Other biopharmaceutical companies with which we compete for qualified personnel may have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize octreotide capsules and any future product candidates we may develop would be impaired and could adversely affect our growth and financial performance.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses, products or technologies, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies. We cannot assure you that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

Potential technological changes in our field of business create considerable uncertainty.

We are engaged in the biopharmaceutical field, which is characterized by extensive research efforts and rapid technological progress. New developments in research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render octreotide capsules or future

product candidates we may develop uncompetitive or obsolete. The longer-term success of our business depends upon our ability to develop octreotide capsules for other approved indications and utilize our TPE platform to develop and commercialize oral forms of therapies that are currently only available in injectable or other non-absorbable forms, which strategy assumes we first obtain regulatory approval of octreotide capsules as a treatment for acromegaly. We cannot assure you that unforeseen problems will not develop with our TPE technology or applications thereof or that any commercially feasible products will ultimately be developed by us.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, principal investigators, CROs and vendors may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to us. The misconduct of our employees and contractors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. Cyber-attacks could include the deployment of harmful malware and key loggers, ransomware, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our technology systems and data. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, our systems and those of our clinical service providers safeguard important confidential personal data regarding patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or clinical trials that we may consider could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our reputation or competitive position could be damaged and the further development and potential commercialization of octreotide capsules and any future product candidates we may develop could be delayed or halted. We may also be vulnerable to cyber-attacks by hackers, or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business and operations or result in financial, legal, business or reputational harm to us. In addition, the cost and operational consequences of implementing further data protection measures could be significant. Moreover, because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate security measures. Our commercial insurance does not cover losses that may occur as a result of an event associated with cyber-attacks.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations and those of our suppliers and other contractors could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical

epidemics or pandemics, such as the recent outbreak of the novel coronavirus COVID-19, military conflicts, acts of terrorism and other natural or man-made disasters or business interruptions. For example, if the current novel coronavirus outbreak continues and results in a prolonged period of travel, commercial and other similar restrictions, we could experience business disruptions. In addition, some of our operations and our primary commercial supplier of octreotide acetate API are in Israel, which has a history of certain conflicts. The occurrence of any business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers in multiple countries to produce octreotide capsules. Our ability to obtain supplies of octreotide capsules could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, and we do not carry insurance to cover such risks.

Laws and regulations governing conduct of international operations may negatively impact our development, manufacture and sale of products outside of the United States and require us to develop and implement costly compliance programs.

As we have operations in Israel and may seek to further expand our operations outside of the United States, we must comply with numerous laws and regulations in Israel and each other jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where we must rely on third parties.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain foreign nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. An expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling octreotide capsules and any future product candidates we may develop outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, the SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We collect and store sensitive data, including intellectual property, our proprietary business information and that of our manufacturers, business partners, healthcare professionals and patients. This includes, where required or permitted by applicable laws, personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Compliance with changing European privacy laws could require us to incur significant costs or experience significant business disruption and failure to so comply could result in an adverse impact on our business.

In Europe, data protection regulation is an area of increased focus and changing requirements. On April 27, 2016 the European Union adopted the General Data Protection Regulation 2016/679, or GDPR, which took effect on May 25, 2018, replacing the data protection laws of each European Union member state. The GDPR applies to any company that collects and uses personal data in connection with offering goods or services to, or monitoring the behavior of, individuals in the European Union. The GDPR enhances data protection obligations with respect to European personal data, including, for example, by requiring expanded disclosures about how personal data is to be used, by placing limitations on retention of information, by imposing mandatory data breach notification requirements, and by creating expansive data subject rights. Non-compliance with the GDPR can trigger fines of up to €20 million, or 4% of total worldwide annual revenue, whichever is higher. Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements has caused us to expend significant resources and such expenditures are likely to continue into the near future as we respond to new interpretations and enforcement actions following the effective date.

The GDPR's restriction on transfers of personal data outside of Europe to countries that have not been found to provide adequate protection to personal data, such as the United States, poses particular compliance challenges. One of the transfer mechanisms that allows companies to transfer personal data from Europe to the United States is the EU-US Privacy Shield (see https://www.privacyshield.gov/welcome for more information). We conducted a self-assessment and subsequently self-certified under the Privacy Shield Framework in September 2016. We received a notice of acceptance of our self-certification in October 2016 and our registration became final on October 26, 2016. There continues to be concerns about whether the EU-US Privacy Shield will face successful legal challenges (as its predecessor the Safe Harbor framework did). If this does occur, we may need to identify and implement an alternative mechanism for legitimizing cross-border data transfers. This may entail additional cost and expense as well as changes to our business practices.

Separate European Union laws and regulations (and member states' implementations thereof) govern the protection of consumers and of electronic communications and these are also evolving. We cannot yet determine the impact that such future laws, regulations, and standards may have on our business. Such laws and regulations are often subject to differing interpretations and may be inconsistent among jurisdictions. We expect that for the immediate future, we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. We may incur substantial expense in complying with the new obligations to be imposed by the GDPR and we may be required to make significant changes in our business operations and product development, all of which may adversely affect our revenues and our business overall. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business.

Exchange rate fluctuations between the U.S. dollar and non-U.S. currencies may negatively affect our results of operations.

The U.S. dollar is our functional and reporting currency; however, a portion of our operations are currently conducted in Israel and most of the Israeli expenses are currently paid in New Israeli Shekels, or NIS. We also contract with CROs internationally, primarily for the execution of clinical trials and manufacturing activities. A portion of these transactions, including value added taxes, or VAT, are settled in Euros or Great British Pounds, or GBPs. As a result, we are exposed to the risk that the NIS, Euro or GBP may appreciate relative to the U.S. dollar, or, if the NIS, Euro or GBP instead devalue relative to the U.S. dollar, that the relative inflation rate may exceed such rate of devaluation, or that the timing of such devaluation may lag behind the relative inflation. In any such event, the U.S. dollar cost of our operations in Israel and transactions with certain CROs would increase and our U.S. dollar-denominated results of operations would be adversely affected. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations. If the U.S. dollar cost of our operations increases, our U.S. dollar-measured results of operations will be adversely affected. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Quantitative and Qualitative Disclosure About Market Risk."

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology and product candidates, our competitors could develop and commercialize technology and drugs similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our strategy is to seek patent protection for our product candidates and compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

With respect to patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, *inter partes* reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, our patents covering our TPE platform technology expire in 2029. At least some of our patents covering MYCAPSSA also expire in 2029. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have an adverse impact on our business.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on polypeptide containing capsules including octreotide capsules and our TPE platform throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same

extent as federal and state laws in the United States. For example, novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

While our product candidate is in clinical trials, we believe that the use of our product candidate in these clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our current and any future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There can be no assurance that our current and any future product candidates do not infringe other parties' patents or other proprietary rights, however, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our development efforts and limit our ability to continue our operations.

Octreotide capsules or any future products we may develop may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of octreotide capsules or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop, or commercialize octreotide capsules, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development or commercialization delays;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent octreotide capsules or any future product candidates from being marketed. Any patent-related legal action against our collaborators or us claiming damages and seeking to enjoin commercial activities relating to octreotide capsules or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market octreotide capsules or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign octreotide capsules or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing octreotide capsules or a future product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of somatostatin analogs, which resulted in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued U.S. patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA in which our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with octreotide capsules and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our development activities before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in United States federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the United States Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to protect our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates and delivery technologies, we also consider trade secrets, including our confidential and unpatented know-how important to the maintenance of our competitive position. We protect our trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or the subject matter independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or the subject matter independently developed by a competitor, our competitive position would be harmed.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other companies and universities. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Our Operations in Israel

The tax benefits available to us under Israeli law require us to meet several conditions and may be terminated or reduced in the future, which would increase our costs and taxes.

We are able to take advantage of tax exemptions and reductions resulting from the "beneficiary enterprise" status of our facilities in Israel. To remain eligible for these tax benefits, we must continue to meet certain conditions stipulated in the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations. If we fail to meet these conditions in the future, the tax benefits would be canceled and we could be required to refund any tax benefits we might already have received. These tax benefits may not be continued in the future at their current levels or at any level. In recent years, the Israeli government has reduced the benefits available and has indicated that it may further reduce or eliminate some of these benefits in the future. The termination or reduction of these tax benefits may increase our income taxes in the future. Additionally, if we increase our activities outside of Israel, for example, by future acquisitions, our increased activities generally will not be eligible for inclusion in Israeli tax benefit programs. For example, we moved out of our Jerusalem location in 2016, which negatively impacted the local tax benefits we previously received by operating there.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and harm our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the Patent Law), and recent decisions by the Israeli Supreme Court and the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, employees may be entitled to remuneration for intellectual property that they develop for us unless they waive any such rights. Although we enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment or engagement are owned exclusively by us, and our current separation agreements with Israeli employees who have left our company include a waiver of all claims, rights or payments under Israeli law, we may still face claims demanding remuneration. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and former employees, or be forced to litigate such claims, which could negatively affect our business.

Our development and administrative facilities and one of our third-party octreotide acetate API manufacturers are located in Israel and, therefore, our business could be hurt by political and military instability affecting Israel.

Our development and certain administrative facilities and one of our octreotide acetate API manufacturer's facilities are located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could materially and adversely affect our business, financial condition and results of operations and could make it more difficult for us to raise capital. Instability in the region may lead to deterioration of the political relationships that exist between Israel and these countries and has raised concerns regarding security in the region and the potential for armed conflict. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Any losses or damages incurred by us could have an adverse effect on our business. Any armed conflicts, terrorist activities or political instability in the region could materially and adversely affect our business, financial condition and results of operations.

Under current Israeli law, we may not be able to enforce our Israeli employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We generally enter into non-competition agreements with our key employees, in most cases within the framework of their employment agreements. These agreements prohibit our key employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under applicable Israeli law, it is difficult

(and may even be impossible) to enforce these agreements or any part thereof against our Israeli employees unless it can be shown that there are special circumstances in any particular case. If we cannot enforce our non-competition agreements against our Israeli employees, then we may be unable to prevent our competitors from benefiting from the expertise of these former employees, which could impair our business, results of operations and ability to capitalize on our proprietary information.

Risks Related to Our Common Stock

**** We may not be able to utilize a significant portion of our net operating loss carryforwards, which could negatively impact our profitability.***

At June 30, 2020, we had federal operating loss, or NOL, carryforwards of approximately $253.8 million. The federal NOL carryforwards generated in 2017 and prior expire at various dates through 2037. The Federal NOL carryforwards generated in 2018 and after have an unlimited carryforward period. At June 30, 2020, we had state NOLs of approximately $203.9 million which expire at various dates through 2039. At June 30, 2020, there were no NOL carryforwards in our Israeli subsidiary.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, substantial changes in our ownership may limit the amount of federal NOL carryforwards that can be utilized annually in the future to offset our U.S. federal taxable income. Specifically, this limitation may arise in the event that the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. NOLs generated after December 31, 2017 are not subject to expiration, and generally may not be carried back to prior taxable years except that, under the CARES Act, NOLs generated in 2018, 2019, and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such federal NOLs is limited to 80% of our taxable income in any future taxable year.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change our current management.

Provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws, may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors;
- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

The affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class, is necessary to amend or repeal the above provisions that are contained in our amended and restated certificate of incorporation. In addition, absent approval of our board of directors, our amended and restated bylaws may only be amended or repealed by the affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which limits business combination transactions with stockholders of 15% or more of our outstanding voting stock that our board of directors has not approved. These provisions and other similar provisions make it more difficult for stockholders or potential acquirers to acquire us without negotiation. These provisions may apply even if some stockholders may consider the transaction beneficial to them.

As a result, these provisions could limit the price that investors are willing to pay in the future for shares of our common stock. These provisions might also discourage a potential acquisition proposal or tender offer, even if the acquisition proposal or tender offer is at a premium over the then current market price for our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine; provided, however, that this Delaware forum provision does not apply to any actions arising under the Securities Act or the Exchange Act. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may impose additional litigation costs on stockholders in pursuing such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage the filing of such lawsuits. The Court of Chancery of the State of Delaware may also reach different judgment or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Furthermore, the enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our certificate of incorporation is inapplicable or unenforceable. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

****The trading price of our common stock may be volatile, and your investment in our common stock could decline in value and incur substantial losses.***

On July 21, 2015, we completed the sale of 7,319,750 shares of our common stock in our IPO, at a price to the public of $16.00 per share. Since shares of our common stock were sold in our IPO, our stock price has reached a high of $30.52 per share and a low of $1.20 per share through August 1, 2020. There has been a public market for our common stock for only a relatively short period of time. Although our common stock is listed on The NASDAQ Global Select Market, an active public market for our common stock may not emerge or be sustained.

In addition, the market price for our common stock may fluctuate significantly in response to a number of factors, including:

- our efforts to secure FDA approval of our CBE-30 supplement and planned second manufacturing supplement for our planned commercial manufacturers of API for octreotide capsules;
- the timing and results of our MPOWERED Phase 3 clinical trial of octreotide capsules or any future clinical trials we may conduct, or changes in the development status of octreotide capsules or any other product candidates we may develop;
- any delay in our regulatory filings for octreotide capsules or any other future product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- adverse regulatory decisions, including failure to receive additional regulatory approvals of octreotide capsules or failure to maintain our existing FDA approval of octreotide,;
- changes in laws or regulations applicable to octreotide capsules or any other future product candidates, including clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate supply of clinical trial material or for any approved drug or inability to do so at acceptable prices;
- our inability to acquire products or technologies or establish strategic collaborations, if needed;
- failure to successfully commercialize octreotide capsules or any other future product candidates, if approved;
- our ability to obtain market adoptions and coverage and adequate reimbursement from third-party payors for octreotide capsules or any other future product candidates, if approved;
- unanticipated serious safety concerns related to the use of octreotide capsules or any other future product candidates;
- our ability to effectively manage our operations or changes in organizational structure;
- the size and growth of our initial target markets;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- business disruptions due to natural disasters, epidemics or pandemics, such as the recent outbreak of the novel coronavirus COVID-19, military conflicts, acts of terrorism or other unanticipated catastrophes;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- sales of our common stock in the future, including sales by our directors and officers or specific stockholders;
- overall performance of the equity markets;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation, and developments related thereto;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

We have been, and could become, the subject of securities litigation, which is expensive and may divert our management's attention.

On June 9, 2016, Chiasma, Inc. and certain of our current and former officers were named as defendants in a purported federal securities class action lawsuit filed in the United States District Court for the District of Massachusetts, styled *Gerneth v. Chiasma, Inc., et al*. An amended complaint was filed by the lead plaintiff on February 10, 2017 challenging our statements regarding our first Phase 3 clinical trial methodology and results, and our ability to obtain FDA approval for octreotide capsules, in violation of Sections 11 and 15 of the Securities Act of 1933. The amended complaint added as defendants current and former members of our board of directors, as well as the investment banks that underwrote our initial public offering on July 15, 2015. The plaintiff sought an unspecified amount of compensatory damages on behalf of himself and members of a putative shareholder class, including interest and reasonable costs and expenses incurred in litigating the action, and any other relief the court determines is appropriate. The defendants filed a motion to dismiss the amended complaint on March 27, 2017 and on February 15, 2018, the court denied defendants' motion to dismiss. The defendants filed an answer to the amended complaint on March 30, 2018. On February 27, 2019, the parties agreed to a settlement of all legal claims in which defendants expressly denied that they have committed any act or omission giving rise to any liability under Sections 11 or 15 of the Securities Act of 1933. On March 14, 2019, the court issued an order of preliminary approval of the settlement. As a result of this settlement agreement, we have recorded a litigation settlement liability of $18.8 million as of December 31, 2018. Additionally, we have recorded a litigation insurance settlement recovery receivable of $18.3 million as of December 31, 2018 which represents the estimated insurance claim proceeds from our insurance carriers. On June 27, 2019, the court issued an order of final approval of the settlement. The litigation insurance settlement recovery and litigation settlement liability were settled during the three months ended June 30, 2019.

Future litigation and any matters arising out of any allegations may result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. We may not be successful in defending future claims and cannot provide assurance that insurance proceeds will be sufficient to cover any costs or liability under such claims.

In addition, the market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities, including our company, have been subject to securities class action litigation. We may be the target of this type of litigation again in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We are an "emerging growth company" and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our securities being less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company through 2020. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) December 31, 2020, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years, or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC based on market value of our common stock held by non-affiliates. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could adversely affect our financial position and results of operations.

We have never paid cash dividends on our capital stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases, which may not occur.

We have not paid cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and other activities associated with being a public company.

As a public company, we incur significant legal, accounting, insurance and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and The NASDAQ Stock Market, has imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require us to continue to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial additional professional fees and that we expend significant management efforts. Prior to our IPO, we had never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

In addition, if we increase our reliance on contractors for important business functions, it may be more difficult to collect, analyze and report the information we are obligated to disclose as a public company and this could result in a material misstatement or omission in our disclosures.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is otherwise doing well.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. As of June 30, 2020, we had 42,268,932 outstanding shares of common stock, assuming no exercise of outstanding options or warrants. In addition, the 7,916,922 shares subject to outstanding options awarded as incentive compensation, including under our stock option plans, the 1,511,498 shares reserved for future issuance under our stock option plans and the 3,567,015 shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our trading price and trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. Shortly following our IPO, four securities analysts initiated coverage on our company. Following the receipt of the CRL to our original NDA from the FDA, each of these analysts downgraded their ratings on and lowered their price targets for our stock, and all four of the analysts either since dropped coverage or discontinued coverage following their departure from their employer. As of August 1, 2020, four securities analysts, including one of the original four analysts, provide coverage on our company. In the event that one or more analysts who now, or in the future, cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our trading price would likely decline. If one or more analysts, now or in the future, cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our trading price and trading volume to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

In the quarter ended June 30, 2020, we did not repurchase any shares of our common stock.

Item 6. Exhibits

The following exhibits are filed as part of this Quarterly Report on Form 10-Q:

Exhibit No.	Description
10.1*	Revenue Interest Financing Agreement, dated April 7, 2020, by and between the Company and HealthCare Royalty Partners IV, L.P., incorporated by reference from our Quarterly Report filed on May 7, 2020.
10.2†	Employment Agreement, dated as of April 8, 2020, by and between the Company and Anand Varadan, incorporated by reference from our Quarterly Report filed on May 7, 2020.
10.3	Open Market Sales Agreement, dated April 7, 2020, by and between the Company and Jefferies LLC, incorporated by reference from our Current Report on Form 8-K filed on April 8, 2020.
31.1**	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	Inline XBRL Instance Document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document.
101.CAL**	Inline XBRL Taxonomy Extension Calculation Document.
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE**	Inline XBRL Taxonomy Extension Presentation Link Document.
104**	Cover Page Interactive Data File.

* Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
** Filed herewith.
† Indicates a management contract or compensatory plan
+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

Table of Contents

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 thereunto duly authorized on August 10, 2020.

CHIASMA, INC.

By: */s/ Raj Kannan*
Raj Kannan
Chief Executive Officer and Director
(Principal Executive Officer)

By: */s/ Mark J. Fitzpatrick*
Mark J. Fitzpatrick
President
(Principal Financial Officer)

Exhibit 31.1

Certification

I, Raj Kannan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2020 of Chiasma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Raj Kannan
Raj Kannan
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Mark J. Fitzpatrick, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2020 of Chiasma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Chiasma, Inc. (the "Company") for the period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers herby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to his knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: August 10, 2020

/s/ Raj Kannan
Raj Kannan
Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 10, 2020

/s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President
(Principal Financial Officer)